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KICKBACKS IN CATARACT SURGERY

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

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KICKBACKS IN CATARACT SURGERY

MONDAY, MAY 23, 1988

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Philadelphia, PA.

The committee met, pursuant to notice, at 9 a.m., at the U.S. Courthouse, Philadelphia, PA, Senator John Heinz presiding.

Present: Senator Heinz.

Also present: Larry Atkins, Minority Staff Director; Nancy Smith, Professional Staff; Maddy Glist, Press Assistant; Chester Ching, Fellow; and Skip Irvin, Professional Staff.

OPENING STATEMENT OF SENATOR JOHN HEINZ

Senator HEINZ. Ladies and gentlemen, good morning. This hearing of the Special Committee on Aging will come to order.

I'm Senator John Heinz, the ranking minority member of the committee. This hearing, as you have been informed, is on cataract surgery and the kickbacks that it involves today. After my opening statement, we'll turn to our witnesses who I'll thank for being with us. Some of them have come considerable distances and we very much appreciate your participation.

Last year over a million older Americans regained their sight through the miracle of modern cataract surgery. What was only a decade ago a rarely used procedure requiring a 3-day hospitalization is today a common and simple operation, taking less than an hour in an out-patient clinic.

Offering great benefit to the patient at relatively low risk, cataract surgery has become one of the most frequent operations involving the elderly and one of medicine's most lucrative specialites. It is a multi-billion dollar industry financed almost entirely by Medicare.

It is also an industry shared by an uneasy partnership of ophthamolgists, on the one hand, and optometrists, on the other. Ophthamologists are surgeons who specialize in diseases of the eye and who rely, in large part, on optometrists for patient referrals. Optometrists do vision screening and testing, prescribe corrective lenses, and with the advent of legislative changes in 1980 and 1986, may provide and charge Medicare for services provided to cataract patients after surgery—services only ophthamologists were paid for in the past.

Like many other lucrative activities, cataract surgery has its small share of profiteers. The big cataract profits come from creating a network of optometrists to maintain a constant flow of referrals to the surgeon and by minimizing the amount of time surgeons spend with any particular patient.

Managers, brokers, and other middlemen help assemble and operate these networks. Surgeons are pressured to perform only surgery. Optometrists are encouraged to see patients immediately before and after surgery. The result is an unjustifiable risk to patients from a small but growing number of greedy profiteers aiming medical practice at financial reward instead of good patient care.

Unfortunately Congress and the Health Care Financing Administration have contributed to this problem. In 1986, Congress enacted legislation that permitted reimbursement of optometrists as physicians for any procedures that they were licensed by the State to perform. HCFA's subsequent separation of the billing without clear guidelines on the proper role of optometrists in cataract surgical care has given the promoters of referral networks a rallying cry.

HCFA and Congress, they say, have encouraged a very broad use of optometrists in providing follow-up care—a trend that has opened the door to highly questionable referral agreements and kickbacks between willing surgeons and optometrists.

In some instances, as we'll hear today, surgeons are being held hostage by optometrists who refuse to send patients unless they are guaranteed the post-operative care and, hence, Medicare payment. In other cases, ophthalmologists are courting optometrists with promises of very profitable post-operative referrals and bonuses like VCR's and other inducements in order to get exclusive rights to the optometrist's cataract patients.

As ranking member of the U.S. Senate Special Committee On Aging, I scheduled this hearing after a staff investigation provided convincing evidence that the incentives for induced and very profitable referrals are having an impact on the practice of cataract surgery.

Today I am releasing, and enclosed for the record, our staff report entitled "Kickbacks In Cataract Surgery." Most significantly, the pattern of fee splitting and highly disturbing referral practices that has developed is a situation that Congress has helped to create. Therefore, we in Congress need to get answers to some critical questions and get them quickly.

First, are we seeing a trend with financial rewards increasingly encouraging practitioners to adopt careless or flawed techniques?

Second, is there a danger for elderly patients of unnecessary surgery, surgery that risks the health of the patient because of inadequate post-operative follow-up? Third, how is Medicare's reimbursement for cataract surgery contributing to this pattern?

And fourth, what change should Congress make in the reimbursement of cataract surgery, for example, by setting clear standards for what Medicare will and won't pay for in the way of services by optometrists in connection with cataract surgery?

The main victims of the powerful financial pressures present in cataract surgery are the tens of thousands of elderly each year who develop complications in their eye surgery, and who might have kept their sight with better care.

While only a small percentage of surgery patients develop post-operative complications of any kind—blindness or the loss of an eye is particularly tragic if it was preventable by merely exercising standard good medical practice. With the advances of the last decade, cataract surgery has been safe and amazingly effective for the millions of older Americans who have gotten improved vision without a hitch. There is no reason to sacrifice this high standard of success by allowing seniors to fall prey to what I fear is a growing number of cataract profiteers.

I'm very pleased that we have such a fine panel of witnesses here today to help us investigate and to flesh out these problems. I would like to begin with Doctor Glenn Pomerance of Ooltewah.

Did I get that right, Doctor,

Dr. POMERANCE. RIGHT.

Senator HEINZ. Ooltewah, Tennessee, and then we'll have Doctor Wright, Mrs. McGee and Ms. Sugarmann in that order.

So, Doctor Pomerance, please proceed. I would appreciate it if all of you would keep your statements to 5 minutes or less, and the reason I make that request is that we have only a little less than 2 hours for this hearing. That is because I must return to Washington for some votes on the INF treaty which will be on the floor late this morning so I will try and keep my questions concise, and I ask you to keep your testimony as concise as possible, but please proceed.

[The staff report "Kickbacks in Cataract Surgery" follows:]

KICKBACKS IN CATARACT SURGERY

Staff Report by the
Minority Staff of the Senate Special Committee on Aging
Senator John Heinz, Ranking Member
May 23, 1988

EXECUTIVE SUMMARY

Recent changes in Medicare reimbursement for cataract surgery have had the effect of sanctioning referral practices and patterns of care that are ethically questionable and may jeopardize the health of older Americans.

- 1980 and 1986 legislation allows optometrists to be reimbursed by Medicare for post-operative surgical cataract services.
- The opportunity for Medicare reimbursement of both ophthalmologists and optometrists for pre- and post-operative cataract care has led to kickbacks and induced referrals between some members of these professions.
- These "kickback" arrangements have had a direct impact on patient care by:
  - -- Encouraging surgery to soon or in inappropriate cases
  - -- Minimizing the amount of essential pre-operative evaluation and post-surgical oversight by ophthalmologists.
  - -- Premising referrals on a surgeon's willingness to refer patients back to the optometrist, rather than on the surgeon's qualifications, proximity to the patient, or the patient's personal choice.

A growing number of cataract surgeries are being performed in this country, making the potential for abuses even greater.

- Cataracts account for 35 percent of all existing visual impairments and 53 percent of all new visual impairments.
- In the last 6 years the number of cataract surgeries reimbursed by Medicare increased from 327,000 in 1981 to an estimated 1.1 million in 1987. This number is estimated to jump to 2 million by 1990.

Kickbacks and induced referral arrangements include: formal and informal agreements of exclusive co-referrals, referral recruiting, and cooperative outreach agreements.

- Associations of ophthalmologists promise exclusive referrals for post-operative care to optometrists, free education seminars, contributions to optometric PACs, Medicare billing services and access to legal counsel to member ODs who refer cataract patients.
- OD managed companies have engaged the services of selected MDs, who work out of the same office or fly/drive in on selected days to perform surgery, with the understanding that all post-operative care will be performed by the optometrists.
- Optometrists cooperate with MDs and do outreach screening using mobile vans that travel to nursing homes and senior centers, and immediately schedule a patient for surgery (without a thorough pre-operative exam) with a cooperating surgeon.
- Optometrists are pressuring ophthalmologists through letters or phone calls to surgeons explaining that no referrals will be made unless they agree to refer-back for post-operative care.

Staff Recommendations

- Modify the mechanism for reimbursing ophthalmologists and optometrists to disengage decisions regarding surgical intervention and post-operative care from financial incentives.
- Set standards for pre- and post-operative care as conditional for Medicare reimbursement.
- Require studies on the relative outcomes of patients based on the different approaches to post-operative care.
- Implement PRO legislative authority for mandatory second opinion of cataract (and other) surgery. Fully implement PRO authority for quality review of pre-operative surgical and post-operative components of cataract care.
- Monitor implementation of Medicare Fraud and Abuse provisions enacted under Public Law 100-93 to clearly define as kickbacks.
- Better educate Medicare beneficiaries about cataract surgery, about the importance of a thorough pre-operative eye and health exam and the proper course of post-operative care, and encourage beneficiaries to seek an independent second opinion.

THE PROBLEM

Recent legislative and administrative changes in Medicare reimbursement for cataract surgery have had the effect of sanctioning referral practices and patterns of care that are ethically questionable and may jeopardize the health of older Americans. In 1980 and again in 1986, Congress passed legislation allowing optometrists to be reimbursed by Medicare for post-surgical cataract services that only ophthalmologists had been reimbursed for in the past. Medicare guidelines issued in 1987 have further clarified reimbursement for optometrists and created the opportunity for highly questionable referral arrangements and kickbacks between consenting ophthalmologists and optometrists.

Under such agreements, medical practice decisions are being increasingly driven by professional and profit motives rather than medical judgment:

- Some ophthalmologists, who depend on optometrists for patient referrals, are being held hostage by optometrists who refuse to refer patients unless they are guaranteed that the patient will be returned to them for post-operative care.
- Some surgeons are recruiting optometric referrals with financial kickbacks, investment opportunities, and promises of post-operative referrals back to the optometrist.
- Patients of some optometrists are referred to ophthalmologists from another geographic area or operated on by surgeons who fly or drive in from a distance for surgery, with the hometown optometrist taking over all of the patient's post-operative care.

These changes in medical practice are putting patients at risk of inappropriate cataract surgery and poor post-operative care. In each case, the surgeon's role in the pre- and post-operative care of cataract surgery is being limited to the surgery itself, and optometrists are taking greater responsibility for medical decision-making and oversight immediately surrounding surgery. Furthermore, these changes encourage cataract surgery in cases where more conservative approaches could be used. Despite the lack of data on the prevalence of such arrangements or the incidence of poor patient outcomes, there are sufficient cases of questionable agreements, unnecessary surgery and poor post-operative care to warrant Congressional attention.

Similar financial agreements emerging among other co-dependent health practitioners may also jeopardize patient care, and will come under increasing scrutiny as Congress continues to respond to the rise in physician costs.

CATARACT SURGERY

Cataracts

A cataract is any opacity of the lens, whether it is a small local opacity or complete loss of transparency, caused by trauma, inflammation, metabolic or nutritional defects, radiologic damage, or simply an advanced senile change. (1)

Cataracts account for 35 percent of all existing visual impairments and 53 percent of all new visual impairments in the population as a whole.(2) Senile cataracts are the most common form of cataract and the third leading cause of legal blindness in the United States.(3) An estimated 27.4 percent -- nearly one-third of all persons 65 years of age and older have a senile cataract.

Cataract Surgery

Cataract surgery involves the removal of the clouded lens and its replacement with an artificial, intraocular lens which is either made of plastic or polypropylene. Surgical removal of the cataract is presently the only course of treatment. Typically, patients are fitted with corrective glasses until their visual impairment is severe and the cataract is "ripe" (hardened). Common myths in cataract surgery include: the earlier the surgery the better; once a cataract reaches the "ripe" stage, it must be taken out as soon as possible; all cataracts should be removed. Only under very rare circumstances is there a reason for emergency (or "same-day") surgery.

While as many as 95 percent of cataract surgeries are complication-free, serious complications do arise post-operatively that, unless treated appropriately and quickly, may result in reduced vision or loss of an eye. These complications include bleeding, leakage, infection, retinal detachment, glaucoma, dislocation of lens, or edema. Typically, patients are treated with antibiotics and steroids following surgery to prevent or control infection.

Trends in Cataract Surgery

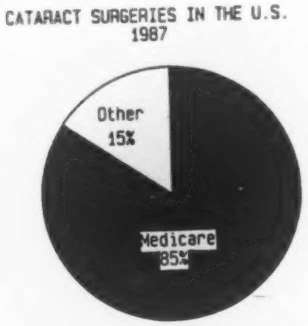
The technology of cataract surgery has advanced significantly in just the past five to 10 years. Prior to 1980, cataract surgery was performed on largely an inpatient basis with an average length of stay of three to six days. Since then, technological advances and Medicare incentives for ambulatory surgery have radically altered the setting for cataract surgery. By 1987, nearly 71 percent of the estimated 1.3 million cataract surgeries were being performed in hospital outpatient departments, 22 percent in ambulatory care centers (ASCs), and the remainder were being performed in physician offices or on an in-patient basis.(4) Currently, there are a total of 591 Medicare-certified ASCs that perform ophthalmic surgery -- the majority of which involve cataract extraction.(4)

MEDICARE REIMBURSEMENT

Although the annual incidence of cataracts is considered to be constant, the number of cataract surgeries performed has increased dramatically in recent years, due largely to advances in the science of cataract extraction and intraocular lens insertion. In the last six years, the number of cataract surgeries reimbursed by Medicare has increased from 327,000 in 1981 to an estimated 640,000 in 1985. The Office of the Inspector General estimates that by 1990, the number of Medicare-reimbursed cataract surgeries will increase to two million.(6)

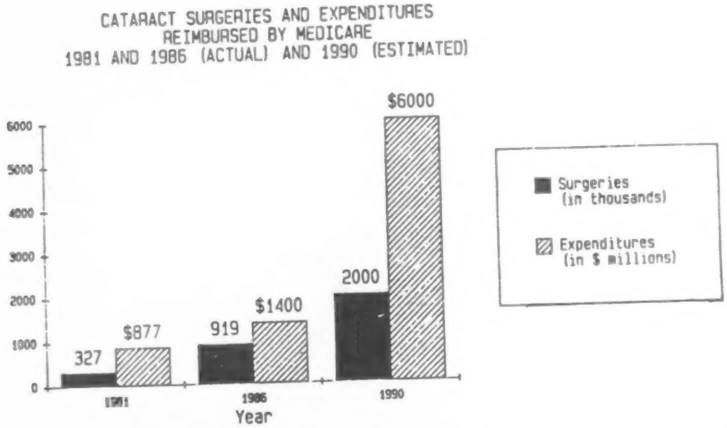
Medicare provides prospective reimbursement for in-patient surgery under Part A of Medicare through DRG 39. Physician cataract surgical services are reimbursed under Part B -- whether performed in-patient or out-patient basis. Medicare pays 80 percent of reasonable prevailing physician charges as calculated by carriers in their region.

Medicare is by far the predominant payor of cataract care in the U.S., accounting for 85 percent of all cataract surgeries performed in 1987.(8) Medicare expenditures for cataract surgery have also increased dramatically since the early 1980's. In 1981, Medicare expenditures for cataract/aphakia totaled $877 million. This amount increased to $1.4 billion by 1986 -- nearly 6 percent of Medicare Part B outlays that year -- and is expected to reach a total of $6 billion by 1990.(7)


CATARACT SURGERIES IN THE U.S.
1987

Medicare-Reimbursed Cataract Surgeries and Expenditures

Year	# Surgeries	Millions of Dollars
1981	327,000	$ 877
1985	640,000	$ 907
1986	919,000	$1,400
1990	2,000,000	$6,000


CATARACT SURGERIES AND EXPENDITURES
REIMBURSED BY MEDICARE
1981 AND 1986 (ACTUAL) AND 1990 (ESTIMATED)

Per-procedure reimbursement varies considerably by site and by state. Medicare payments for cataract/aphakia surgery for surgical and post-surgical care are paid on a global fee basis based on prevailing rates. A 1986 study by the Office of the Inspector General found that payments varied from a low of $1,416 for surgery performed in physician's office to a high of $5,550 for in-patient surgery.(8) The same study documented an equally broad range in payment amounts within and across states; ranging from $960 to $3,251 per hospital outpatient procedure. The Health Care Financing Administration reports an average per case payment of $1,640.

Per Procedure Medicare Reimbursement

Total Reimbursement By Site	
Hosp. In-Patient:	$2,472/$5,550
Hosp. Out-Patient:	$2,482/$6,740
Ambul. Surg. Ctr:	$2,037/$3,703
Physician Office:	$1,416/$3,158

Outpatient Reimbursement By State	
California:	$1,286/$3,251
Florida:	$1,200/$2,224
Penn:	$1,143/$1,851
Texas:	$1,156/$1,818
Washington:	$ 960/$1,634

For individual surgical practices, the increasing volume of surgeries capable of being performed on a daily basis and increasing numbers of older consumers promises a potentially lucrative Medicare market. In its 1986 study of cataract surgery, the Office of the Inspector General found that 10 out of 38 ophthalmologists were paid between 1.0 and 6.4 million dollars in 1984.(8)

Legislative History

Under Medicare, reimbursement is provided for the diagnosis and treatment of cataract conditions with certain exceptions. Excluded from coverage are: 1) routine physical examinations that led to the detection of a cataract but were not prompted by a patient complaint; 2) eyeglasses or contact lenses except post-surgical lenses that are considered by Medicare to be prosthetic devises; 3) examinations resulting from refractive error; and 4) procedures performed to determine the refractive state of the eye. As orginally passed, Medicare reimbursement to optometrists was limited to "establishing the necessity for prosthetic lenses."(9)

In 1980, legislation was passed that permitted optometrists to be considered as physicians for the purpose of reimbursement for the post-operative care of aphakic patients (cases where a lens has been lost, nearly all of which are due to cataracts). The 1980 legislation also called for a report to Congress by the Secretary of Health and Human Services on legislative recommendations to further expand coverage of procedures performed by optometrists. The findings of the Administration's study (issued in December, 1982) recommended against any further expansion of the law -- a position repeated in testimony before the House Committee on Energy and Commerce in January, 1984 (10,11). Despite the Administration's position to the contrary, the Congress passed and the President signed into law provisions in the Omnibus Budget Reconciliation Act of 1986 (OBRA'86) that expand coverage of optometrists to include all services optometrists are certified to provide under state licensure or regulation.

At the same time, in both the 1986 and 1987 budget reconciliation acts, Congress reduced reimbursement for cataract surgery. In 1986, Congress cut the maximum allowable prevailing charge by 10 percent; in 1987, cataract surgery was included as one of 12 "overpriced" procedures subject to a 2 percent across-the-board cut, and additional cuts on a sliding scale when charges exceed 85 percent of the national average.

HCFA Guidelines

Neither the 1980 or 1986 provisions specified how optometrists should be paid for post-surgical care. The Administration finally issued guidelines on how reimbursement would be structured in April, 1987. These guidelines have provided for separate billing of optometric services without establishing any uniform standards for involvement of optometrists in post-surgical care.

The opportunity for induced referrals and kickbacks stems, in part, from the way Medicare reimburses for post-operative care that is "co-managed" by ophthalmologists and optometrists. In order to protect against duplicative billing, ophthalmologists (who are paid a single, global fee for cataract surgery and post-operative care) must indicate on the billing form that the patient has been referred to an optometrist for post-operative care by applying a code (Modifier 54) to the ophthalmologist's billing form. Optometrists may be reimbursed up to 10 percent to 20 percent (depending on the carrier) of the global amount for up to 90 days after surgery, but only if the ophthalmologist uses Modifier 54.

The effect of the modifier has been to encourage fee-splitting and induced referrals. Although evidence suggests that these types of arrangements were going on prior to 1987, "Modifier 54" has become a "hook" some optometrists are using to refuse to refer patients for surgery unless the are assured the referral for post-surgical care and that some ophthalmologists are using to "court" referring optometrists with promises of post-operative Medicare paybacks.

ROLES OF OPTOMETRY AND OPHTHALMOLOGY

There are currently 17,000 ophthalmologists and 25,000 optometrists practicing in the U.S.(12,13) Ophthamologists are available at a ratio of 5.0 to 100,000 population, while optometrists are available at a ratio of 10.4 to 100,000 population. Ophthalmologists are widely distributed across the U.S. -- less than one percent of the population is without the services of ophthalmologists. (13)

Training

Optometrists and ophthalmologists are separately trained, separately reviewed and certified by state boards, and separately accredited.

Ophthalmology is a surgical specialty within the field of medicine. Ophthalmologists complete four years of medical education (which usually includes two years of didactics and two years of clinical rotations), and one year of internship after receiving their M.D. In addition, to be certified by the American Board of Ophthalmology, ophthalmologists must complete three years of training in an ophthalmology residency program.

The requirements for licensure as a Doctor of Optometry (O.D.) vary by state, but all require that a practitioner be a graduate of an approved program of optometry and pass a written proficiency examination. Most optometry programs require that applicants have completed two years of college and passed an admission test, and an estimated 78 percent of all optometrists hold B.A. degrees. Optometry training programs include four years of didactic, laboratory and clinical training with instruction covering basic and optical science, optics and lens design, and application.

State Licensure

State laws vary significantly in the governance of optometric practice. Generally, an optometrist is defined by state statutes as one who is licensed to examine eyes and correct refractive errors using ocular techniques or by prescribing and fitting corrective lenses. Until recently, optometrists were also expected to detect, but not treat, diseases of the eye. At present, 48 states have expanded this authority to permit optometrists to use diagnostic drugs and 23 have passed laws allowing them to use therapeutic drugs. Two other states (Pennsylvania and Louisiana) are currently considering therapeutic drug legislation and two others (Maryland and Alaska) have passed diagnostic bills that are before their governors for signature.

State laws generally refer to allowable diagnostic and prescriptive procedures, but do not specify the situations in which these procedures may be applied. This lack of specificity is used by some to assert that optometrists are not authorized to perform these functions and by others to argue that they are not precluded from performing them.

The Omnibus Budget Reconciliation Act of 1986 (OBRA'86) permitted optometrists to receive Medicare reimbursement within the scope of state laws and regulations. Since OBRA'86, several states have been pressured to clarify state statute relative to the authority of optometrists to participate in the post-operative care of surgical patients. The results of these reviews vary. North Carolina's attorney-general has sanctioned the inclusion of post-operative care in the definition of optometry, while the Pennsylvania Board of Medicine has ruled out the performance of post-surgical care by optometrists.

Roles in Cataract Surgery

While ophthamologists and optometrists generally agree on the protocol for pre- and post-surgical care, they strongly disagree on which points of intervention are best or should only be managed by the surgeon.

Both the optometric and ophthmalic professions agree that the final decision to proceed with surgery rests with the attending surgeon (ophthalmologist) and the patient and that the decision should factor in the extent of visual impairment, the patient's overall health, and the overall condition of the eye. They also agree that all cataract patients should be seen by the attending surgeon the day immediately following surgery, and that the final refraction and prescription of corrective glasses can be performed by an optometrist. It is the period between post-operative day one and this last visit where there is considerable disagreement between the professions and among ophthalmologists.

Treatment Stage	MD's View	OD's View
Detection & Referral	-- agree, OD or primary physician --	
Pre-Operative Exam Examine Cataract Thorough Eye/Med Exam	MD	OD, verified by MD
Surgery	MD	MD
Day 1 Post-Op. Exam Adjust medication Check for leakage, bleeding	MD	MD
Day 5 Adjust medication Check for leakage, infections	MD	MD or OD if no complications
Week 2-3 Adjust/stop meds Check for leakage, infection.	MD	MD or OD if no complications
Week 6 Check for infection	MD	MD or OD if no complications
Week 7/8-10 Refract & order lens	MD	MD or OD

The lack of consensus is based on differing views on the ability of optometrists to detect post-operative complications and take appropriate, corrective actions. This is further complicated by differences in opinion on the adequacy of optometric training for post-operative patient management and on differing interpretations of state licensing authority for optometrists.

KICKBACKS, INDUCED REFERRALS AND QUALITY PROBLEMS

Patterns of kickbacks and induced referrals take a variety of forms: formal and informal agreements between practioners that involve exclusive co-referrals; optometrists pressuring ophthalmologists by refusing to send cataract patients unless they do the post-operative care; ophthalmologists recruiting referrals from optometrists by promising post-operative referrals and more; and cooperative outreach arrangements where optometrists screen and schedule patients for surgery without any pre-operative exam by the surgeon.

The Committee has collected evidence of the following financial or professional inducements:

- Ophthalmologists have formed associations and solicit membership from optometrists by promising them exclusive referrals for post-operative care, free education seminars (in post-operative practice and Medicare billing), contributions to optometric PACs, Medicare billing services, and access to legal counsel.
- Management companies, owned or directed by optometrists, have engaged the services of a selected ophthalmologist who either works out of the same office or flies/drives in on selected days to perform surgery with the understanding that all pre- and post-operative care will be performed by the optometrists.

- Individual practitioners have informal agreements where optometrists exclusively refer to their cooperating surgeon, often at great distances, with the understanding that they will either receive the patient back immediately or receive some financial remuneration.
- Optometrists have engaged in outreach screening using mobile vans that travel to nursing homes and senior citizen centers and immediately schedule patients for surgery (rather than conducting a thorough pre-operative exam) with a cooperating surgeon.
- Optometrists have sent letters or made calls to surgeons explaining that no referrals will be made to them unless they agree to refer-back for post-operative care.
- Surgeons have sent letters to optometrists explaining their desire to "redirect" their practice to surgery itself and rely on optometrists for pre- and post-operative care. In once case, an ophthalmologist sent out letters warning that Medicare was about to implement a prior-approval system and that it would be best refer to all potential candidates for surgery soon before Medicare made it more difficult to get reimbursed.

Financial and professional inducements for and against the involvement of optometrists in post-operative care have the potential of altering medical decisions, minimizing the involvement of the attending ophthalmologist in the period surrounding cataract surgery, and having a direct impact on the quality of care cataract patients are receiving. The results of these arrangements are:

- To encourage surgery sooner and in cases that previously would have been more conservatively managed.
- To minimize the amount of essential pre-operative evaluation and post-surgical oversight by ophthalmologists.
- To encourage referrals to surgeons based on an ophthalmologist's willingness to use the Modifier 54 rather than on surgical qualifications, proximity to the patient, or the patient's personal choice.
- To contribute to patterns of referring patients to surgeon's several hours (or states) away, posing a serious risk if post-operative complications develop.

CONGRESSIONAL AND ADMINISTRATIVE ACTIONS

Previous Hearings on Cataract Surgery

Hearings in 1978, 1979, and 1984 before the House Ways and Means and Energy and Commerce Committees reviewed the reimbursement of cataract services, and led to the legislative changes in reimbursement in 1980 and 1986.

Concerns about unnecessary surgery and fraud and abuse in marketing of intraocular lenses prompted hearings before the Senate and House Aging Committees in 1985. Senate hearings on unnecessary surgery led to legislation requiring mandatory second opinion in Medicare that the Congress passed in 1985.

Current Studies on Kickbacks in Cataract Surgery

In the wake of the Health Care Financing Administration's issuance of instructions for reimbursement in April of 1985, various studies have been initiated to follow up on allegations of induced referrals and kickbacks and poor quality care.

- In October, 1987, HCFA Administrator Roper requested an internal investigation by the Office of the Inspector General (OIG) into allegations of system "gaming" and poor quality care.

- Two other studies have been requested by the House Committee on Ways and Means. A General Accounting Office (GAO) investigation similar to that of the OIG's is underway as well as a study by the Office of Technology Assessment (OTA) on the question of whether optometrists are medically prepared to manage the care of cataract patients post-operatively.

- An investigation into cases of questionable ophthalmic and optometric agreements and related cases of unnecessary or poor quality cataract care has been undertaken by the Senate Aging Committee minority staff.

Anti-Kickback Legislation

On August 18, 1987, the "Medicare and Medicaid Patient and Program Protection Act of 1987", originally introduced by Senator John Heinz, was signed into law (Public Law 100-93). This legislation was developed in response to growing concern for the occurence, and lack of enforcement authority over kickbacks, bribes and rebates under Medicare. Key prohibitions in the statute include: Solicitation or receipt of any remuneration or offering or paying any remuneration (including kickbacks, bribes or rebates), directly or indirectly, overtly or covertly, in cash or in kind: in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Medicare. The statute also lists four exceptions to these prohibitions regarding circumstances where costs are appropriately disclosed, bona fide employment situations, written vendor agreements, and payment practices specified by the Administration in regulations.

Public Law 100-93 requires that proposed regulations implementing the law be issued by August, 1988 and that final regulations be issued by August, 1989.

PRO Review

The Consolidated Omnibus Reconciliation Act of 1985 requires that the Secretary of the Department of Health and Human Services develop guidelines for prior-certification of certain surgical procedures. The Secretary has specified that cataract surgery is subject to mandatory review, in contrast with nine other surgeries that may be reviewed at the discretion of the Peer Review Organizations (PROs).

The Omnibus Budget Reconciliation Act of 1986 also requires that PRO quality review be extended to Medicare services provided in non-hospital settings, including ambulatory centers and physician offices. All PROs are scheduled to phased-into ambulatory review by April of 1989 and pilot projects to test approaches to physician office reviews are to begin in January, 1989. As yet, it is uncertain whether PRO review of cataract surgery will adequately cover the review of post-operative as well as surgical components of cataract care.

OPTIONS FOR CONGRESSIONAL/ADMINISTRATION RESPONSE

A number of options exist for preventing and halting questionable agreements and kickbacks among consenting ophthalmologists and optometrists and ensuring that cataract care provided under Medicare is appropriate and of the highest possible quality. These include the following:

- Modify the mechanism for reimbursing ophthalmologists and optometrists to disengage decisions regarding surgical intervention and post-operative care from financial incentives.

- Specify, as a condition of Medicare reimbursement, minimum guidelines for pre- and post-operative care that include: the conduct of a thorough, pre-operative exam; notification and consultation with a patient's personal physician or proxy prior to surgery; patient disclosure of the Medicare practice standards, their right to choice among practitioner, and of any referral agreements between attending ophthalmologists and optometrists; a one-day post-operative examination by the attending surgeon; and such other standards as developed through consensus among practitioners and consumers.

- Require studies on the relative outcomes of patients based on the different approaches to post-operative care.
- Make PRO authority for second opinion (at least of representative sample of) cataract surgery and post-surgical quality review mandatory as part of the pending regulations in compliance with the Consolidated Reconciliation Act of 1985.
- Tighten PRO quality review of cataract surgery and post-operative care performed in ambulatory care settings and require focused reviews of cataract surgery performed in physician pilots scheduled to begin in January, 1989.
- Monitor implementation of Medicare Fraud and Abuse provisions enacted under Public Law 100-93 to clearly define as kickbacks informal arrangements for which the primary remuneration is "in kind" payments such as pre- or post-operative referrals, contributions to independent but related entities (such as political action committees) and other "paybacks" as indicated.
- Better educate Medicare beneficiaries about cataract surgery, about the importance of a thorough pre-operative eye and health exam, and encourage beneficiaries to seek an independent second opinion.

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CASE EXAMPLES
INDUCED REFERRALS AND KICKBACKS IN POST-OPERATIVE CATARACT CARE

- As early as 1980, ophthalmologists entered into "underground" agreements with optometrists for post-operative care that included financial kickbacks and gifts.

  Case: A North Carolina group of ophthalmologists offered $100 in post-operative payments, video cassettes, free seminars, free transportation and overnight accommodations for patient referrals. (December, 1984)

  Case: A Florida Clinic letter acknowledges same-day surgery and thanks optometrist for referral with $100 check. (January, 1985)

  Case: Ophthalmologists in an eastern state report, "Some renegade ophthalmologists, more monetarists than ethicists, have for years paid under-the-table kickbacks to optometrists for post-operative care as marketing strategy to ensure continued patient referrals. Patients for dollars." (December, 1984)

- Some optometrists, in order to capture the post-operative Medicare market, refuse to refer patients to ophthalmologists for treatment unless they are guaranteed referrals for post-operative care. This encourages referrals based on economic agreement rather than the quality or proximity of the surgeon.

  Case: Dr. X in an eastern state has been called repeatedly by optometrists asking if he refers for post-operative care. When he answers "no," he is told, "You know you'll lose referrals." When asked if he will ever refer post-operatively he responds, "I'll be forced to. Otherwise, I will not receive any referrals or have to extend my practice to do primary care in order to generate referrals." (April, 1988)

  Case: An ophthalmic practice in eastern state contends, "Our group practice has already been bombarded by such requests from optometrists eager to cash in on this financial bonanza. The implications to those of us who feel the patient is not best served by this approach is certainly clear. No sign-off, no referrals." (August, 1987)

  Case: An ophthalmologist in Pennsylvania cites one typical example of induced referral. "I received a phone call from an optometrist (in anther town) where there are several ophthalmologists. The doctor asked me if I was familiar with the new Medicare modifier, and then said that if I was willing to send the patient back to him for post-operative care, he had two patients to refer for surgery. I was surprised to hear from him in the first place as I rarely received any referrals from him in the past. What was implied was that if I did not 'play ball' with him, he could take those patients elsewhere."

  Case: An ophthalmologist in Pennsylvania received a call from an optometrist with a patient who needed cataract surgery. The optometrist asked if the ophthalmologist participated in the "Optometrist-Ophthalmologist situation whereby the optometrist did the follow-up care." After the ophthalmologist made it clear that he felt responsible for the follow-up care, the optometrist then told the ophthalmologist that he would lose referrals if he did not "participate in this type of thing." (August, 1987)

  Case: In a letter from the referring optometrist to the ophthalmologist who performed the surgery, the optometrist wrote, "I am very displeased with the fact that I was not afforded the opportunity to participate in the 90 day post-operative period...In the future, I fully expect to participate in the care of my patients."

Case: Two ophthalmologists in a Pennsylvania were contacted by "two different optometrists who suggested referrals based on returning the patient for post-op care...One said that Dr. X returns them one week after surgery."

Case: An ophthalmologist in Arizona was contacted by a local optometrist who had previously referred several patients to him. The optometrist told him that all of her cataract cases were being referred to two other clinics, one of them about 20 miles away. She asked if the ophthalmologist would be willing to accept cataract referrals and allow her to do the post-op care. The ophthalmologist replied "no" and has not received any referrals since that conversation.

- Some ophthalmologists are courting optometrists (through dinners and "post-operative management seminars") with promises of post-operative Medicare business along with financial and other types of remunerations (kickbacks) in return for selective surgical referrals.

Case: Staff of a Medicare carrier were asked to speak on the application of Modifier 54, only to find themselves at a pre-arranged and "highly suspect" dinner hosted by a ophthalmic group for optometrists, with the clear intent of encouraging selective surgical referrals in return for post-operative referrals. (March, 1988)

Case: An ophthalmologist reports, "We have ophthalmologists in this area who are purchasing ultrasound instruments and gifting them to optometrists to serve as an inducement for the optometrists to refer cataract patients. The optometrists are performing the ultrasound axial length measurements and charging Medicare for same. They then refer the patient with the cataract to the ophthalmologist for surgery."

Case: In a letter sent to optometrists in Arizona, offering a seminar in cataract management, an eye center announces that it "is pleased to offer doctors of optometry a unique opportunity ... to be involved in total patient management throughout the course of cataract development, surgical treatment, and post-operative care." and that "Doctors of Optometry have the skill and instrumentation to provide the post-operative care in their own offices. Therefore, following surgery, your patient may return to your office." The purpose of the course is "to educate Doctors of Optometry about Current Approaches to Cataract Care and to launch this opportunity for cooperative, quality patient care delivery."

- Some ophthalmologists and third party management groups are establishing Associations that cooperative (selectively referring) optometrists may join for a membership fee that buys them: donations in their name to state optometric PACs; continuing education seminars; reimbursement and optional billing services for post-operative care; attorney services; and other benefits.

Case: Letter from a Pennsylvania eye center announces creation of membership association. For a membership fee of $500, optometrists (who refer patients to the Center) receive: PAC donation of $100, quarterly seminars worth $50-$100, optional billing, reimbursement for post-operative care; attorney services. (July, 1987)

Case: Several optometric eye centers have been set up in California that invite optometrists to enter as shareholders in the corporation for $3,000 in cash. Another $2,000 is contributed later. Optometrists refer patients to a closed panel of ophthalmologists. Proceeds from reimbursements and private charges are shared by the ophthalmologists and the corporation. Corporate earnings are then paid back to optometrist-shareholders in the form of advertising, legal fees, profits, and dividends. (October, 1987)

Case: A New York advertising promotional agency through its use of an illegal name presents itself in its commercials as a medical entity. This group offers cataract surgery at no cost to the Medicare patient, including free transportation. All the patient would have to do is to claim that they were a hardship case with no proof of this fact required. In return for these referrals, the nine physicians pay the agency 50% of their surgical fee.

Case: In letters to ophthalmologists across the country, a California marketing firm describes their search for ophthalmologists who would have exclusive rights to the promotional program that they offer. This promotional program consists of a mailing to all households in the area with a resident over 65 years of age, provision of all administrative services for the program, and exclusive rights to all referred patients for up to three years.

- In some instances, cataract surgery is being done sooner than is medically necessary as a result of incentives for referral by optometrists in anticipation of post-operative follow-up.

Case: Ophthalmologists in an eastern state assert that "Greedy ophthalmologists linking with greedy optometrists set up closed loop networks where major eye surgery is sanctioned and performed under very questionable diagnoses and indications."

Case: In a letter to an optometrist, a Missouri ophthalmologist emphasized that Medicare is requiring state PRO pre-approval of all cataract surgery candidates scheduled after January 1, 1987. He writes, "If you have any patients who are probable candidates for surgery or other medical referral, it may be appropriate to encourage patients to get care before December 31, 1986, while Medicare coverage is still predictable."

- Some ophthalmologists and optometrists are entering into formal "co-management" agreements that stretch the pre-operative diagnostic role of optometrists to their professional limit such that ophthalmologists first see their patients on the same day or minutes before surgery is performed and drastically scale back their post-operative role. This can lead to premature or unnecessary surgery and can block the early detection of post-operative complications.

Case: In October, 1987, an ophthalmologist who was facing charges of the North Carolina State Board of Examiners, acknowledges that he did not perform the 24 hour post-operative examination in several cases but delegated such examinations to nurses and optometrists and never saw some patients anytime during the post-operative period.

Case: Several senior citizens received a surprise visit by a mobile screening unit at their senior center in Oklahoma. After getting a free screening by optometrists, two people were told that they needed to have cataract surgery done in a city 200 miles away. Transportation was to be provided and post-operative care was to be provided by local optometrists. One of the patients got a second opinion and found out that she did not need surgery. The other came down with a cold and went to see his family physician who referred him for a second opinion. Again, surgery was not indicated.

Case: An optometrist in an eastern state accompanies patients for (and observes, which in itself is fine) same day surgery - but then takes over the immediate after-care of patient, along with a $500 check from the attending surgeon.

Case: A Florida eye clinic offers free cataract and glaucoma screenings. If the patient's vision is below 20/300, he is provided transportation to an ophthalmologist who is about an hour to an hour and a half in each direction. In one case, a patient was told that he had a cataract which was "ready to explode in their eye and needed emergency surgery." After undergoing surgery, post-operative care was provided by the local optometrist in the area.

Case: One case cited by an Oregon ophthalmologist involves his patient who previously suffered from herpes of the face and eye and whose poor vision is caused by a damaged optic nerve. The patient went to see a local optometrist who referred her to another ophthalmologist with whom he worked. This ophthalmologist performed the cataract surgery without requesting the patient's previous medical and optical records. The patient does not remember ever seeing the ophthalmologist for post-operative care. The patient's vision was not improved by the cataract and implant surgery.

* Some patients are being sent to "cooperative" ophthalmologists at great distances from their homes (at times in buses and at times with hotel costs covered by participating surgeons). This suggests that the decision to proceed with surgery is being made, in essence, by the referring optometrist and only validated by the surgeon after surgery has been scheduled. If complications arise, the patient must either travel hours to see the surgeon or be admitted to an emergency room.

Case: An ophthalmologist in an eastern state is, at his own expense, busing patients in from other states and arranging for their overnight lodging -- then sending them back without any post-operative involvement on his part.

Case: In an Utah eye clinic, out-of-town patients often are examined and have surgery the same day before returning to their homes where the local optometrist provides the post-operative care. In the past, this eye clinic has recruited optometrists by offering $85.00 per surgical referral.

Case: A rural hospital in North Carolina was approached by a group of ophthalmologists who operate a large ophthalmological outpatient clinic in a city about 150 miles away with a plan to fly down to see patients in the morning at the office of a local optometrist and perform cataract operations in the hospital in the afternoon and provide post-operative care the next morning. The ophthalmologist would then return to his home and leave the balance of the post-operative care to the optometrist. If any complications arise, either the patient would have to be flown up to the ophthalmologists or they would have to fly down because the ophthalmologists were unable to arrange any local ophthalmologists to cover for them.

Case: In a small community in Oregon, local optometrists who have their offices one mile of five ophthalmologists refer their patients to ophthalmologists in a small town that is four and a quarter hours away. These patients must drive through the largest metropolitan area in the state and through the state capitol to reach this other small community. Post-operative care is provided by the local optometrists.

Case: A patient in West Virgina was told by her local optometrist that she needed cataract surgery and she had to go to an ophthalmologist located 200 miles away. Despite her wish to be followed post-operatively by a physician closer to home, she was told that she needed to be seen by the optometrists and other staff of the operating ophthalmologist so she continued to make the 200-mile drive. She only saw the ophthalmologist briefly before surgery and during the surgery itself.

* Some ophthalmologists are blocking peers from co-managing patient care with optometrists -- actions that run counter to current Medicare law and encourage optometrists to refer patients to cooperative ophthalmologists out of town or state.

Case: The Washington State Academy of Ophthalmology filed a petition in October, 1986 with the Washington State Medical Disciplinary Board urging a ruling that would bar ophthalmologists from making surgery after-care referrals to optometrists. The Board declined to issue a binding ruling but did reiterate a previous Board proscript stating that "economic motivation shall not be the basis for referral." The Washington Academy continues to pressure their members to not co-manage with optometrists.

* Some optometrists are not referring patients back to surgeons on a timely basis when post-operative complications arise.

Case: A patient was referred to an optometrist for post-operative care. The attending ophthalmologist then left town on vacation, entrusting follow-up care to the optometrist exclusively. Complications developed on day six that were misdiagnosed by the optometrist. 12 hours later, the patient went to an emergency room and was referred to an ophthalmologist who immediately performed surgery. She has lost her vision and may also lose her eye as a result. (March, 1988)

- Articles on "how to co-manage" are appearing in trade journals, some of which encourage same day surgery and abbreviated post-operative oversight by the attending surgeon for the "convenience" of the patient.

  Case: Article in February, 1988 Review of Optometry by an optometrist advising, "... see if you can schedule surgery before the surgeon even meets the patient.... After the patient has had surgery, you can immediately take over the patient's care."

- Some ophthalmologists who are reluctant to give up their patients post-operatively (for professional, monetary or malpractice reasons), but risk losing referrals if they do not cooperative with optometrists, are continuing to do the acute post-operative work, but passing off the dollar value under Medicare to the optometrist.

  Case: The OIG has found lower than expected cases where the Modifier 54/55 has been used, suggesting that ophthalmologists are continuing to provide post-operative care and finding other ways of "appeasing" referring optometrists.

  Case: A senior official of a Medicare carrier admitted to being told that ophthalmologists are performing all post-operative care but passing along that portion of the Medicare reimbursement for which optometrists are now eligible in order to ensure continued surgical referrals.

MEMBER SURVEY, AMERICAN ACADEMY OF OPHTHALMOLOGISTS, MAY, 1988

DESCRIPTION OF SURVEY

A survey was conducted by the American Academy of Ophthalmology to document the experiences of physicians with potential abuses of the Medicare reimbursement for cataract surgery by certain health care practitioners. This survey was distributed to various state leaders (141) and other Academy members chosen at random (300). Eight questions were asked about the incidence of networking and referral arrangements and related quality of care issues.

The limitations of the survey should be emphasized at the onset. They include problems of self-selection and potential bias, especially among state leaders who are more likely to respond to the survey. Nevertheless, the data provide insight into the types of referral patterns being observed.

RESULTS

* 207 responses were received, 46.9% of the total of 441.

* 11.6% of respondents personally encountered or were aware of selective referral arrangements by optometrists that are contingent on release of post-operative care to referring OD's.

* 3.9% of respondents personally encountered or were aware of financial or other forms of renumeration to referring optometrists to encourage referrals.

* 20.8% of respondents personally encountered or were aware of marketing plans involving referral agents with no medical expertise.

* 35.3% of respondents observed that patients were being sent unnecessarily long distances for surgery and returned immediately after surgery.

* 26.1% of respondents observed that in suggestive referral arrangements, patients were diagnosed as needing cataract surgery before medically indicated.

* 24.6% of respondents observed that patients were receiving same day surgery with little or no pre-operative involvement by an ophthalmologist.

* 6.3% of respondents observed increasing cases of post-operative complications.

* 25.6% of respondents observed large changes in referral patterns during the last 9-12 months.

STATEMENT OF GLENN POMERANCE, M.D., OOLTEWAH, TN

Dr. **POMERANCE**. Good morning, and thank you, Senator Heinz. My name is Glenn N. Pomerance and I'm an ophthalmologist in private practice in Chattanooga, Tennessee. I'm here today to relate my experiences in an ophthalmic/optometric network.

In 1984, after 8 years of military service in which I worked closely with optometrists in the non-competitive, collaborative military healthcare environment, I was approached by a health care management firm to move my practice to Chattanooga where a group of optometrists was interested in establishing a network which would use a single provider of medical and surgical care.

A contract was negotiated in which I engaged the firm to manage the business elements of my practice. As owner of the practice all medical decisions were my responsibility and right. The manager, as agent for me, was to provide the facilities and personnel for the practice. At the same time, the manager entered into a contractural relationship with a diagnostic optometrist who was to practice at the same location. There was approximately 80 optometrists in the network.

Before I ever arrived in Tennessee, my application for a medical license in Tennessee was challenged by a local opthalmologist who sits on the Board of Medicine. The challenge was based on some feared future ethical or legal impropriety. My license was withheld until I initiated legal action.

After my arrival in Tennessee, I was denied staff privileges at the public hospital and was rejected for membership in every medical society I sought to join. I have subsequently won membership and privileges but only after legal challenge.

Interested optometrists formed and invested in a partnership which lent the manager money for capital and operational expenditures at 22 percent interest per annum. The manager contributed a percentage of its earnings to optometric organizations and causes. The leaders of the optometric referral group attempted to exercise control of the medical practice.

I was warned on numerous occasions that it was unacceptable for me to allow a patient sent for cataract surgery to return home without it. I resisted this effort to make the decisionmaking process anything but an informed one between physician and patient directed at a clearly defined patient benefit.

The manager contended that the success of its venture might be thwarted if the prescribed number of cataract surgeries was not performed. Furthermore, I was admonished by the board not to refer to certain physicians in the community. The manager directed me to employ a general practitioner to cover my highly specialized practice when I was away from my office so that the diagnostic optometrist could continue to see and treat Medicare patients.

I was urged to allow the optometrist to use my medical license by authorizing, as if I could, performance of medical and surgical treatment, clearly outside of his license. The manager and optometric group wanted me to provide immediate, same day surgery for all surgical candidates. They wanted me to relinquish post-operative care of surgical patients to the family optometrist on the day of surgery.

They wanted me to operate at a facility which was not of my choice. They wanted me to use medical devices which were selected by the manager.

I did not yield to any of these demands, believing none to be in the best interest of my patients.

When the Health Care Financing Administration implemented its decision to split out post-operative care and to pay optometrists for it, the manager submitted by billings to Medicare only for the surgical services, but I performed duplicate post-operative surgical services without reimbursement in the interest of responsible patient care. I believe many of the activities of the manager and the network were designed to alienate me from my colleagues, and to coerce me, by cooperation with the group.

As a result of these intractable problems, I terminated my contract and moved my practice down the street. The manager cooperated with the leaders of the optometric network to discredit me in the community. The manager sought to obtain a court order to have the medical records of my patients returned to them. The optometrists were sent a letter by the manager falsely stating that I had taken, without permission, records and equipment belonging to the manager.

The optometrists were provided with a complete list of every patient ever referred to me along with a suggested letter to be sent to those patients urging that they abandon my care. Finally, the manager has filed a multimillion dollar lawsuit alleging breach of contract and has broadcast this fact to optometrists and patients.

The manager still operates the referral network. The current surgeon commutes by stretch limousine over 100 miles approximately 1 day a week to operate on patients who have been determined by optometrists to need surgery. He gets paid only for the surgery, and that is all he does.

In my opinion, the patient is abandoned at a critical point in the surgical treatment. Although many optometrists have been instructed in limited post-operative management, none has the medical or surgical experience of the operating surgeon.

A short course in post-operative patient care by a cooperating surgeon is not a substitute for an experience obtained in residency. A certificate issued by a commercial enterprise in which one has a financial interest is suspect as an objective measure of competence.

Management of the post-operative condition, in my opinion, is inseparable from the operative event and should therefore only be performed by a competent medical practitioner. Yet government policy and payment appear to support this behavior.

I sit before you an island in the medical community, still not accepted by my colleagues, shunned by the majority of optometrists in the region, perplexed as to the progressive erosion of quality care in my specialty, chagrined by the apparent lack of concern by federal agencies over the importance of these changes and buoyed only by my sense of achievement in restoring useful vision and meaningful lives to my aging patients.

I'll be happy to answer any questions you might have.

Senator HEINZ. Doctor Pomerance, thank you very much. I'll reserve all questions until we hear the testimony of everybody on the panel, so I will now turn to Doctor Wright.

Doctor Wright, thank you for being here. I understand you're from Kinston, North Carolina.

STATEMENT OF CHARLES WRIGHT, M.D., KINSTON, NC

Dr. **Wright**. Without a "G," yes, we dropped the "G" when King George gave us trouble in the Revolutionary War.

Senator Heinz, thank you for the opportunity to speak here today. My name is Walter Wright and I am a general ophthalmologist from Kinston, North Carolina, a small city in the eastern part of the State.

I, like most of my colleagues, offer primary as well as secondary care to all age groups but my own surgical practice is heavily weighted toward the elderly, the black and often indigent Medicare-insured population.

Cataract surgery contributes significantly to my surgical practice, but it does not constitute the main thrust of my overall practice, nor does it occupy a large portion of the time I spend with patients.

During my early years in practice, I was approached by optometrists wanting to send cataract surgical patients to me, but only if I agreed to allow the optometrist to diagnose the problem, schedule the surgery from their offices, and run preliminary tests, which, of course, generate Medicare fees, prior to the surgery.

I was specifically not to examine the patient before or after surgery, but rather return them immediately to the care of the optometrist. When I refused, I was assured I would never receive referrals and I did not.

In my current practice situation, I have received an unsolicited letter from a nearby optometrist who indicated that he, and any other optometrists he could influence, has been sending referral cataract patients out of town because the practice I joined had a reputation for not referring their post-operative patients to optometrists.

I have also had conversations with a surgeon, who is not participating in optometric referral networking, who told me that his price for acquiring patients on referral was simply $135 per patient, $5 more than the surgeon to whom the referrals had been previously sent. He suggested I contact local optometrists and simply offer more money if I wanted to acquire cataract referrals. Of course, I did not and I have not.

But the main reason I'm appearing before you today, Senator, is to speak on behalf of the silent victims of this outright buying and selling of patients . . . the nearly 30 million Americans over age 65 in this country.

Although people are living longer now (with 2.5 million American over age 85), as a result of the improved physical, financial, and mental health situations they enjoy today, for the first time in history they can look forward to these extra years of life as something to treasure, not something to fear.

But our senior citizens want to remain independently able to care for themselves, which requires, among other things, adequate eyesight. This eyesight is what allows them to drive an automobile, to maintain the ability to read the Bible, the newspaper, and instructions on medication bottles.

The prospect of losing adequate vision, and thus their independence, is one of the most potent fears expressed to me almost daily by elderly patients, and it creates tremendous vulnerability and willingness on their part to do virtually anything to avoid losing their sight.

I present to you now, Senator, a casebook prepared by myself and my colleagues that, with your permission, I would like to have included in the record.[1]

Senator HEINZ. This——

Dr. WRIGHT. You have three copies of it.

Senator HEINZ. Very well, without objection the entire case will be part of the record, Doctor Wright.

Dr. WRIGHT. Thank you.

I feel certain it will demonstrate the varied, and sometimes quite imaginative, methods used by optometry/ophthalmology referral networks to exploit the vulnerability of our elderly citizens. And it will show how the Medicare payment system can induce the same senior citizens to unwittingly be subjected to surgery that is very often inappropriate or totally unnecessary.

We can show actual cases in which elderly patients with documented 20/20 vision and no visual complaints have been told by the optometrists that they have cataracts which must be surgically removed immediately to prevent them from losing their driver's license or becoming blinded. The sense of urgency implied in these statements is totally inappropriate for cataract development.

Eye surgeons participating in these referral networks have put television and VCR machines, complete with tapes made by the surgeon, in the offices of optometrists who meet certain referral criteria. Outright offers of monetary fees have been made on a per capita basis to cover the costs said to be usually charged for post-operative care.

We can also show cases, Senator, where optometrists call surgical centers and actually schedule the patients for cataract surgery; have vans, supplied by the surgeons, pick up and transport the patients at no charge; provide free overnight accommodations for the night following surgery; assure the patients that no attempt will be made to collect their portion of the Medicare deductible for other charges, thus assuring them of absolutely free surgery; and then return them to the care of the referring optometrists pursuant to an arrangement that will guarantee the optometrists a fee-generating opportunity under current Medicare law.

Recently, more innovative arrangements have been made in which optometrists within a community already served by well established eye surgeons have scheduled patients for surgery to be performed by itinerant surgeons.

These surgeons often fly into such communities and perform various surgical procedures on patients they have not examined prior to the scheduling of the surgery. The post-operative care of these patients is then relegated to the referring optometrists, the surgeons fly home, and again a guaranteed fee-generating opportunity has been provided to the optometrists.

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[1] See appendix 4, p. 133.

In summary, Senator, one of our greatest natural resources, senior citizens, your parents and mine, are being reduced to a commodity that is bought and sold. They have become the silent victims of referral networks that take advantage of their extreme vulnerability and coerce them into what is many times unnecessary surgery.

The really tragic feature of this is that Medicare, through its payment policy, is a willing participant and I think this simply has to stop.

Thank you, Senator.

Senator HEINZ. Doctor, I thank you very much for some very eloquent testimony and we will examine your casebook extremely carefully. I understand it goes well beyond the subject of cataract surgery per se and into other issues. Is that not correct?

Dr. WRIGHT. That is absolutely correct.

Senator HEINZ. I'd like to welcome Mrs. Isabella McGee who has come all the way from Salt Lake City, Utah, to be with us.

Mrs. McGee, I understand that because of your vision situation you're going to ask your niece, I believe her name is Mrs. DeYoung.

Mrs. DEYOUNG. That's correct.

Senator HEINZ. To read your testimony I understand that you would be pleased and able to answer any questions; is that right, Mrs. McGee?

Mrs. MCGEE. Yes.

Senator HEINZ. We welcome you, Mrs. McGee or Mrs. DeYoung, please proceed.

Mrs. DEYOUNG. Good morning, Senator. In this statement when I refer to "I", it is Mrs. McGee.

Senator HEINZ. I understand.

STATEMENT OF ISABELLA McGEE, SALT LAKE CITY, UTAH, ACCOMPANIED BY LIL DeYOUNG

Mrs. DEYOUNG. My name is Isabella McGee. I am 70 years old and I do receive Medicare benefits.

I do not have a right eye anymore. I lost my eye because of an infection after outpatient surgery. It was a kind of infection that has to be treated right away.

When I went back to the clinic for follow-ups they didn't have the same person look at me each time. When I went back with pain because of the infection, I had an optometrist look at my eye. He didn't think I had an infection. He thought I had something else. Because of an untreated infection, they had to take my eyeball out.

With the Senator's permission, I don't want to mention any names here today. I just want to tell you, as best I can, what happened to me.

My family doctor knew I had cataracts. I also had some kind of drainage problem in both eyes. He referred me to a particular eye surgeon. I wanted to make sure he was a good surgeon, so I called our Department of Business Regulations. They told me he was a very good eye surgeon.

I met the surgeon when he examined my eyes at his clinic. He said I'd have very good vision in my right eye if I did a certain kind of procedure.

Eleven days later he did the operation. It lasted about a half hour, from 11 to 11:30 in the morning. I was home by noon. I never saw my surgeon again until I was in the hospital because of complications. That was nine visits to the clinic over a 2-month period without seeing my surgeon.

Every time I went to the clinic for follow-up appointments, I saw whatever doctor they gave to me. I never knew that some of these doctors were ophthalmologists or some were optometrists. Even if they told me, I wouldn't have known the difference.

I had to go back to the clinic more often because problems were developing. My weight dropped from 105 pounds to 90 pounds. One night I just paced the floor because my right eye was hot and burning.

I went into the clinic the next day. The doctor who saw me was an optometrist I learned later. He told me to use more steroid drops and come back in 4 days. I learned later that this medication should not have been prescribed for my infection.

I called their answering service very early the next morning—on a Saturday—because my eye still hurt. They told me to come in and a doctor would see me. This time it was an ophthalmologist, but not my surgeon. He took one look at my eye and sent me to the hospital straight away.

I stayed in the hospital for a week over Christmas. My surgeon came in to visit me and brought me flowers. That was nice but his money couldn't fix what was wrong with me.

It was a real hard stay in the hospital. They had to put a needle right in my eye and I could feel every bit of it. It was Christmas and my family waited until after the holiday to celebrate Christmas with me.

When I got home from the hospital, I went back to the same clinic three more times. On the third time they told me I might lose my right eye. That was because of the infection.

Nobody will ever know how hard that was. I might have given up right there if it wasn't for my family. When they told me I might lose my eye, I lost my trust in those doctors.

I went back to my family doctor and he sent me to another eye doctor for a second opinion. This new doctor told me I had a blind and painful right eye and there was nothing that could be done to save it. He sent me for a third opinion and when they agreed, the eye was taken out.

Since then, I have had cataract surgery on my left eye. It's harder to have the surgery when you just have one eye. This time I went to a woman surgeon. She promised me she would do all the follow-up exams herself, and she did too. She did a good job.

My right eye is still having problems. The new eye irritates the socket and I'm taking medication for that.

This has been an ordeal for me and I'm really grateful for my family. I live at home with my husband of 53 years. He had a stroke so I have to do everything for him—cooking, bathing, everything. Also my niece works and I take care of her little boy. I really need one good eye to take care of everybody.

I hope you do something so this kind of thing doesn't happen to someone else. I think optometrists are good for certain things. But when I had my infection, I think I should have been examined by a different kind of eye doctor. I hope you change this so someone else does not have to go through what happened to me.

Thank you, Senator.

Senator HEINZ. Mrs. McGee, thank you for some very difficult, but nonetheless very valuable testimony for our committee and for our hearing record. I know it has not been easy for you to think about what you've been through and to relive it a second time as I know you have during these last few moments and we really are extremely grateful to you for going through all of that hardship and heartache all over again.

I think your trip is well worth it, and the pain that you have shared with us will make a lasting impression on my colleagues as well as myself. I really do thank you.

Mrs. Sugarmann. Mary Sugarmann, you have come from Pittsburgh, Pennsylvania, my hometown. We welcome you and I thank you for being here. Would you please proceed with your testimony.

STATEMENT OF MARY SUGARMANN, PITTSBURGH, PA

Mrs. SUGARMANN. Good morning, Senator.

My name is Mary Sugarmann and I am from Pennsylvania. I'm here today to talk about my cataract surgery which took place on February 17, 1988.

My surgeon came to see me immediately after the surgery to say everything went well and to tell me to report to his office the following day where I would see this associate as he himself would not be in but wanted me to come in on Friday, the 19th, when he would look at my eye.

My daughter took me to the doctor's office on the 18th to have the patch removed from my eye where I was seen by my doctor's associate. At that time I had no idea that he was not a surgeon but was, in fact, an optometrist.

At this time, he told me that my eye looked fine and he did not believe that it would be necessary for me to come in the next day but to call that morning and he would let me know. This I did, and was told that it was not necessary to come in to the office.

My eye felt fine, so on Monday, the 22nd, I returned to work and had no problems. The following day, the 23rd, the morning went fine. About 11:30 my eye began to water and pain so I called the doctor's office and was told to come in, which I did right away.

Again my doctor was not there and I was seen by the optometrist who, after examining my eye and putting in some eye drops, told me to go home, take a couple Tylenol, and take a nap. Because of the pain I was not able to rest and as the day went on, the pain got worse.

My daughter called me about 8 p.m. and when she realized how much pain I was in, left work to come and take me to the emergency room at the hospital where I had the eye surgery. There I was seen by an eye surgical resident who, after examining my eye, had my daughter and me follow him to another hospital where I was seen by a surgeon.

At about midnight that night I was taken to the operating room for surgery because my eye was greatly infected. Again on Thursday, the 25th, about 5 p.m., I was taken to surgery. On recovery from that surgery I was told that I would not regain the sight of my eye.

On Saturday and Sunday the surgeon who did the cataract surgery came to visit me in the hospital and both times told me this should never have happend and probably occurred in the operating room.

Looking back on the events that happened, I wonder, if the optometrist had sent me back to the hospital on the 23rd to see a surgeon instead or sending me home, that things might not have turned out differently.

Senator HEINZ. Mrs. Sugarmann, thank you very much.

Let me start with you. Did your surgeon tell you before surgery that you would not be seen by him but by an optometrist the next day?

Mrs. SUGARMANN. Not before surgery, no.

Senator HEINZ. Would it have made a difference to you if you had known?

Mrs. SUGARMANN. No, I probably wouldn't have thought anything of it.

Senator HEINZ. You assumed he would have been another surgeon?

Mrs. SUGARMANN. Right.

Senator HEINZ. And now that you've been through this, would it make a difference?

Mrs. SUGARMANN. Oh, yes, now it would make a difference. I would make sure I was seen by a surgeon.

Senator HEINZ. By an ophthalmologist?

Mrs. SUGARMANN. Yes.

Senator HEINZ. Who was a trained M.D.?

Mrs. SUGARMANN. Right.

Senator HEINZ. I must say I think there are a lot of people who are confused by the difference between an optometrist and an ophthalmologist. You discovered that where there are complications after surgery, there is a very critical difference, one that made a difference to you more than likely in the loss of an eye.

Mrs. SUGARMANN. Yes, because there was about 10 hours difference that might have been different.

Senator HEINZ. Now, did the optometrist that followed you after your surgery tell you he was an optometrist?

Mrs. SUGARMANN. No.

Senator HEINZ. And you would not have known the difference if he had; is that right?

Mrs. MCGEE. That's right.

Senator HEINZ. Did that seem at all strange to you at the time?

Mrs. SUGARMANN. Probably not.

Senator HEINZ. What advice would you give to other people who are thinking of having cataract surgery today?

Mrs. SUGARMANN. First of all that they go to a qualified ophthalmologist and that also, especially afterward, be seen by him.

Senator HEINZ. So you would insist that they be seen by the surgeon after the operation?

Mrs. SUGARMANN. Yes.

Senator HEINZ. I think you've illustrated that point the very hardest possible way by living through the consequences of not being able to do now what you would recommend to everybody. I thank you for your testimony.

Let me ask Mrs. McGee. Mrs. McGee, you said that you never saw the surgeon who operated on your eye until after you were rushed to the hospital for emergency surgery; is that right?

Mrs. McGEE. That's right.

Senator HEINZ. Did that seem at all strange to you at the time?

Mrs. McGEE. Yes.

Senator HEINZ. Now, how do you feel about that situation—that you did not see a doctor well in advance or sufficiently in advance of the surgery?

Mrs. McGEE. Well, I don't think it's right for us to go see our doctor and then we can't see him, we have to see other doctors and I think that surgeon that done it, the surgeon should be the man to see you. I don't think we ought to be tossed from one to another.

Senator HEINZ. Now, how is it that you actually got to see a surgeon on the day of your emergency surgery? Did you call someone? How did that come about?

This is when you had to have your emergency surgery subsequent to your cataract operation.

Mrs. McGEE. I got up at 4 in the morning and I was so miserable, I was so sick. I only weighed 90 pounds and I just couldn't go on so I got up and called the doctor's number and I got a nurse and she told me that there was no doctor on hand right at that minute but she would get ahold of the doctor and she'd have him call me right back.

So I waited and finally she called me back and she said for me to increase my medicine 1 drop every hour and she would try to get in touch with the doctor and have him call me and talk to me.

So awhile later that doctor, she couldn't get ahold of him, she got ahold of another doctor, and he told me to keep on with the medicine, to put hot packs on my face and as soon as they could get ahold of the surgeon that was in charge at that time, he would call me. Well, he never did call me.

So finally my sister came and she just took one look at me and she called the answering service back and she told them, "We've got to have help." She says, "My sister is real ill," and she says, "We've got to get ahold of some doctor."

So she finally connected us to this head surgeon and he told us to be at his office at 9 in the morning.

So my sister got me up and got me dressed and took me down to the clinic and he wasn't there at that time. We had to wait about 15 minutes for him to get there. And when he came, he took us up to his office and he just took one look at me and he said to my sister, he says, "She has got to go to the hospital, she has an infection. And we must get her over to the hospital as fast as we can."

So I went over to the hospital and checked in and first thing they did was put the IV in my arm and then this surgeon, not the surgeon that did the operating, his assistant, came in and told me that they'd do everything they could to help me.

Senator HEINZ. Is that when they said that you were probably going to lose your eye?

Mrs. MCGEE. No, they didn't tell me in the hospital I was going to lose my eye. I had left the hospital and gone back to the clinic. After I got out of the hospital I had to go back to the clinic. I think it was the next day or the following day.

And he told me then that the possibility was that I'd have to lose my eye and he would let me know definitely. So a couple of days later he called me back and told me that the eye had to be removed on account of my health. My health was down.

Senator HEINZ. Now, you described a situation where you awoke very early in the morning, you tried to reach your doctor through the answering service or through the nurse and a doctor, or someone you thought was a doctor, called you back.

I understand, correct me if I'm wrong, that the person who called you back was not a surgeon or ophthalmologist but, in fact, was an O.D., a doctor of optometry; is that right?

Mrs. MCGEE. I think the first doctor that came to me in the hospital was an ophthalmologist.

Senator HEINZ. No, I meant on the phone.

Mrs. MCGEE. The one on the phone, I couldn't tell you what he was. I don't know.

Senator HEINZ. I understand that the one who called you back and said to you to put more drops in your eye was in all likelihood, an O.D., a doctor of optometry.

Mrs. MCGEE. I don't know who that surgeon was at all that gave me those instructions, gave the nurse instructions.

Senator HEINZ. Mrs. McGee, I think you've illustrated extremely well and with a great personal tragedy to yourself what happens when there is not appropriate and necessary post-operative care provided by somebody who is fully trained to diagnose and properly treat the kinds of symptoms that were so apparent to the physician, the ophthalmologist, when he finally saw you.

The physician who you saw when you went to the hospital at 9 or 9:30 that morning clearly, as you've testifed to, took one look at you and realized you had a serious problem, an infection.

I think that between you and Mrs. Sugarmann you have illustrated very clearly and very tragically and sadly what can happen in those instances when complications arise and when properly trained people are not involved in promptly seeing, diagnosing, and treating those problems.

On behalf of my colleagues on the committee, we very much share your concern and frustration and above all, thank you both for being willing to tell your story here at this hearing.

Let me at this point turn to Doctor Pomerance and Doctor Wright.

Doctor Pomerance, in your testimony, you've described yourself as an island in the medical community. Are you an isolated case or are there others who are caught like you between these financial inducements of optometrists and the professional pressures of ophthalmologists?

Dr. POMERANCE. I think there are others who are involved in this. Many of them are willing participants because of the lucrative nature of their practices.

Many of them don't realize what they're getting into until they're there and then because of the isolation from the medical community and the coercion by the optometric system of referrals, find that they can't back out of it. Many of them are unwilling participants.

Senator HEINZ. Now, you worked at a center which was part of a chain of centers, as I understand it. These are not uncommon.

To your knowledge, do these kinds of centers rely on optometrists to make the decision to go with surgery and take over patient care the day after surgery?

Dr. POMERANCE. I can't speak to all of the systems obviously since I was only a participant in one, but in this particular one the decisionmaking process was to be theirs entirely, that the patient needed surgery, when the patient was to be released back to the optometrist and in conjunction with the manager of the practice, which obviously had a financial arrangement with the optometrists who were practicing privately, the decisionmaking process for such things as intraocular lenses, location of surgery, whether it be an ambulatory surgery, or a hospital-based one, they attempted to make. I tried to detach myself from their decisionmaking process in an attempt to remain objective and do what was in the best interest of my patient.

Senator HEINZ. Now, you testified that you left so as to provide what you thought was appropriate medical care to the patients that you had been seeing.

If you had agreed to, so to speak, play ball, how do you believe that would have affected the quality of care of the patients that were your responsibility at the center?

Dr. POMERANCE. Primarily it interfered—it would have interfered with an objective decisionmaking process between doctor and patient. That has been a tried and true long-term benefit to patient to be able to deal with the physician one-on-one and there is no place for anybody else to interfere with the decisionmaking.

Senator HEINZ. You mentioned decisionmaking. Can you be concrete about that? Does that mean you would have been pressured to perform, if you had agreed to play ball, surgery that might have been more conservatively managed?

Dr. POMERANCE. Yes, I think there were many instances of patients who did not get cataract surgery at my practice because their particular vision problem: No. 1, didn't present the problem to them and No 2. could be more conservatively managed with spectacles or other techniques.

Senator HEINZ. So there can be a wrong presumption fed by the reimbursement for cataract surgery, that surgery should be performed even when it's not necessary, when it's not the best course for the patient. Is that what we're saying?

Dr. POMERANCE. I think the financial inducements tend to taint and release it from its normally objective standpoint.

Senator HEINZ. What would you recommend be done at the State and/or Federal level to address this problem?

Dr. POMERANCE. That is a complicated problem and it doesn't lend itself neatly to a simple answer. I think starting on the State level——

Senator HEINZ. Let me ask a fundamental question.

Are you saying that there should be no role for O.D.'s or optometrists in cataract surgery?

Dr. **Pomerance**. I'm not saying that at all. As a matter of fact, my participation in the military health care delivery system gave me a great respect for what optometrists do and what they're able to do and as long as they are properly credentialed and trained to perform and the surgeon is comfortable with their performance, I feel there can be a role for them.

However, I do not feel that the decisionmaking process between the patient and the doctor needs to be forced or coerced in any way. I feel that the current referral arrangements which exist and the current payment options which exist through Medicare definitely are pushing both parties into making decisions that are not necessarily in the best interest of the patient.

Responding to your original question about what can be done, I think it needs to start at the State level where regulatory boards need to readdress the definition of the roles of each of these professional groups.

They need to further define what is the operative period and what is not and also they need to assure the public that proper credentialing and experience is obtained so that co-management of post-operative patients is safe and in the best interest of the patient.

The second thing that can be done is disengaging the medical decision-making from financial incentives. I think the unbundling of the surgical and post-operative fees was a mistake and gave the wrong message to both professions, that it was an acceptable practice, when indeed it might not be.

I think peer review standards need to be elucidated which would hold the M.D. accountable for whatever decision was made on behalf of the patient and that would certainly, I think, alleviate many decisions that are made because of the fear of adverse peer review.

And most important, I think as has been graphically demonstrated by the testimony of Mrs. Sugarmann, and even more so by Mrs. McGee, that the patient must be fully informed and must render informed consent. They must know who the players are.

All doctors wearing white coats are not the same and I think they need to be absolutely told, before the surgery, where they're going, what the ground rules are and let the patient decide whether this is what they want.

I think they also need to be informed of the fiduciary relationships existing between an optometrist or an optometric group and the referred-to ophthalmologist.

Senator **Heinz**. Let me ask you concerning your reference to the mistake that Congress made in unbundling payments.

Now, prior to 1980 and 1986, the law was that here was a global fee, but it only went to ophthalmologists, to doctors. In 1980 we permitted a modifier to be used for payments for aphakia, if I pronounced that correctly?

Dr. **Pomerance**. You did.

Senator **Heinz**. And in 1986 we permitted, for all types of cataract surgery, for optometrists to be reimbursed, and that such reimbursement goes up to 20 or so percent of the cost of the procedure billed to Medicare by the ophthalmologist.

Now, what would you propose as an alternative to that? You're saying we made a mistake, as I understand what you said, in letting optometrists participate in that way.

What should we do instead? And I ask that because the reason that the Congress did what it did was to avoid the possibility of double billing. The idea of having an optometrist paid out of the global fee was to prevent a second billing by an optometrist for services that the ophthalmologist might well have rendered. Therefore both double billing and possibly double services, which is in nobody's interest, especially not the taxpayers' interest, can be prevented.

How do we solve the problem without creating the other one that drove Congress to do what it did?

Dr. POMERANCE. I can understand the problem. This is an expensive procedure for the Government performed on many millions of people in the course of several years. I think if you define—if the States are able to define what is the operation and the post-operative period and make that the responsibility of the ophthalmologist and allow him to bill Medicare and get a fee as had previously existed with the global fee and then define an arbitrary point in time which is by mutual agreement and with expert advice that patient might be released from the M.D.'s care to go back and be cared for by the optometrist and get services from the optometrist, I feel that might be reimbursable, I believe, in and of itself.

Again it's not an easy problem and one of the reasons I think that went into the decisionmaking process to unbundle was to solve the problem of under-the-table payments for the post-operative management by a physician to optometrists which is well known—which is well known to have occurred.

Senator HEINZ. That's before, in a sense, it was legalized?

Dr. POMERANCE. In a sense that's exactly my point, in that it was legalized and that again is a wrong message. The message is that it's acceptable behavior to relinquish the patient immediately after surgery to go back to the optometrist who may or may not be competent to take care of him.

The problem here, I think, is the role of the States in defining what is satisfactory care and I think professional review organizations, which exist now to monitor many medical services, can be used to help in this regard as well.

Senator HEINZ. Let me ask Dr. Wright.

Dr. Wright, you painted a very bleak picture of how patients are being deceived into surgery and you described, in part, some of the tactics used to do that.

What are some of the common myths and arguments used to manipulate people and how can we better educate and protect consumers against that?

Dr. WRIGHT. I think the main point that needs to be stressed, Senator Heinz, is that cataracts do not occur or worsen overnight. The very idea that someone would think that anybody over 65 doesn't have early cataract changes is a bit silly; almost 100 percent of human beings that have been on Earth 65 years have cataracts. So making the diagnosis of early cataract changes should be segregated in the public's mind from having a cataract that is somehow functionally significant.

Second, cataracts don't blind you in the sense of the usual use of that word. I have never heard an ophthalmologist use the term "blind" except in the instance in which there is virtually no light perception in the eye and that is an irreversible circumstance.

I think that cataracts can blind you over a long period of time but it is a different type of blindness and presumably it's reversible. It's reversible if you had the surgery yesterday; it's reversible if we do it tomorrow, or a week from tomorrow, or next year; and the patient, in terms of education along these lines, needs to understand that the myth of going blind rapidly or needing emergency cataract surgery is just that, it's a myth. There's plenty of time to seek a second opinion; there's plenty of time to talk to your family physician about your other problems and get his or her advice; there's plenty of time to consult your family and make a lot of decisions before you (no pun intended), just blindly follow some referral path.

Senator HEINZ. I'm not going to have time this morning to go into the details of your casebook, but I understand that there are some 50 cases in your book that cover instances of ophthalmic-only induced necessary surgeries and question management of eye diseases that are not related to cataracts by optometrists but illustrate the kickbacks or induced referrals that are only part of the story.

Am I correct?

Dr. WRIGHT. That is correct.

Senator HEINZ. Let me get to the real heart of the issue. As I asked Doctor Pomerance, what in your view needs to be done to prevent the kinds of practices that have been described today?

Dr. WRIGHT. I think in the interest of time I would simply say that I certainly agree with Doctor Pomerance, that unbundling of fees must be stopped. The way that it is being done right now can be spread through other areas of medicine, and I think we're already seeing how it is not the answer to the problem.

Most States can establish for themselves a standard of care and they don't do it by sitting down and deciding what one will be. It can be done and it has been done in North Carolina by polling every single surgeon qualified to perform this surgery. What you find when you do that is virtually 98 percent, at least in our State, are convinced that several post-operative visits up to 5 to 7 weeks after the surgery are necessary and a part of the services that they render to their patients.

Senator HEINZ. So you're saying that there is a substantial consensus in the medical community as to what appropriate standards of quality care are?

Dr. WRIGHT. I disagree that it's difficult to set a standard. I very much agree that a standard is there by the very nature that this operation has been going on for years and even the most up-dated techniques have been performed on millions of Americans and I think the standards that the vast majority of ophthalmologists agree on—that you couldn't get 98 percent of them to agree the sun was shining—but they do agree on what post-operative care is necessary.

Senator **Heinz**. Is there any other medical procedure that is performed as frequently on senior citizens as cataract surgery?

Dr. **Wright**. I'm sorry, I would have no way of answering that. There certainly is no elective surgical procedure, to my knowledge, on that age group that has been posted as often in hospitals where I've worked. So in my own experience the answer is that cataract surgery is by far the most frequently performed elective surgery on the over 65 population.

Senator **Heinz**. One final point of clarification. You're not saying that optometrists, O.D.'s shouldn't have some role in post-operative care.

If I understand what you're saying, the boundary of where the ophthalmologist or surgeon leaves off and the optometrist's role begins needs to be carefully defined and it can be defined by common standard medical practice?

Dr. **Wright**. I think so, but it does require that the Health Care Financing Administration (and that the Congress in directing them) understand that quality of control—quality control of cataract surgery can be and should encompass considerations for pre- and post-operative standards of care.

These standards are very well-defined and I do not find the ambiguity that others have talked about.

Senator **Heinz**. Doctor Wright, thank you very much, Doctor Pomerance, Mrs. McGee, Ms. Sugarmann. We thank you all very much for being a part of our hearing.

We have one other panel of providers and the Government that we want to hear from and I thank you all and appreciate very much your participation here today. Thank you.

Our next panel consists of the Deputy Inspector General, Mr. Bryan Mitchell; Doctor Hunter Stokes who is the Secretary for Government Relations at the American Academy of Ophthamology; Mr. Harvey Hanlen, O.D., Chairman of the Federal Relations Committee of the American Optometric Association; Charles Booth, the Director of Office Reimbursement Policy, Health Care Financing Administration, and Mr. Eric Kriss, the President and Chairman of Medivision, Inc.

Thank you very much for being here.

I'd like to start with Mr. Mitchell.

STATEMENT OF BRYAN MITCHELL, DEPUTY INSPECTOR GENERAL, U.S. OFFICE OF INSPECTOR GENERAL, WASHINGTON, DC

Mr. **Mitchell**. Good morning, Mr. Chairman.

I am Bryan Mitchell, Acting Deputy Inspector General of the Department of Health and Human Services.

In 1985 we testified before the House Select Committee on Aging on fraud, waste, and abuse in the field of cataract surgery. We presented our report on Medicare cataract implant surgery, including details on the kickback arrangements for eye care as well. That study was on eye care issues.

Overall, 112 investigations related to eye care have led to 17 criminal convictions, the exclusion of 50 eye care professionals for Medicare program participation and the imposition of $1.8 million in civil monetary penalties.

The cataract surgery industry is already a multibillion dollar industry. According to billing data maintained by the Health Care Financing Administration, in 1985 surgeons billed $1.2 billion of which Medicare allowed $907 million.

In 1986, Medicare allowed amounts for surgeons increased to $1.4 billion. The average surgeon in our sample of the case that I will talk about later who performed his own follow-up care annually, received $930,000 Medicare payments; but surgeons in our sample who refer patients back to optometrists, receive, on the average, $1.9 million annually from Medicare, because of their higher volume.

These figures, of course, may not be representative of all ophthalmologists but they do indicate that cataract surgery is a lucrative practice.

Senator HEINZ. Just to be clear on that, because those are stunning numbers, you're saying that the ophthalmologists that use an O.D. to deliver some care on average receives more than twice as much money from Medicare to the tune of $1.9 million per year from cataract surgery alone than the physician who does all the work his or herself?

Mr. MITCHELL. That's correct.

Senator HEINZ. Please continue.

Mr. MITCHELL. We were very pleased that Congress took strong action in OBRA 1985 and OBRA 1986 and 1987 to reduce cataract surgery fees, limit the markup on IOL and insure equality in payment for fees paid to ambulatory surgical centers and hospitals.

The coverage of services provided by optometrists was further expanded by OBRA 1986 which authorized Medicare to pay optometrists directly for any service that they are authorized to perform under their respective State laws.

The Medicare Program generally pays a global fee for cataract surgery. That global fee covers the pre-surgical evaluation of the patient, the surgery itself, and the post-cataract surgery follow-up visits.

HCFA established a billing procedure which allows for the splitting of the global fee between the ophthalmologist and the optometrists, by requiring the ophthalmologist to place a number "54" at the end of the surgical procedure code.

This modifier "54" identifies for the Medicare carrier that the ophthalmologist is not going to perform post-cataract surgery follow-up visits. The Medicare carrier reduces the Medicare payment by an established percentage. These range from 5 percent to 30 percent. The difference going to the optometrist who does perform the follow-up visits and who notifies the carrier of a request for payment by using the related modifier "55."

In our current study it was designed to examine the referral arrangements that were allowed for by that change. We focused on the frequency of such arrangements, potential impact of this practice on the patient and the Medicare program, the reimbursement implications and the potential for fraud and abuse.

We randomly selected and examined the payments made on behalf of 1,000 Medicare beneficaries in eight different locations.

Our report has not been completed; however, based on analysis to date, we have some preliminary findings, and we will be happy, Senator, to submit for the record a copy of that report.[1]

Senator HEINZ. We thank you.

Without objection your entire report will be part of our entire hearing record.

Mr. MITCHELL. Based on the data and our analysis to date we have found that in 97 percent of the cases we reviewed the ophthalmologists billed Medicare a global fee for cataract surgery. The modifier, the split billing, was used in only 3 percent of the cases.

However, 28 percent of the ophthalmologists we interviewed permit split billings. These ophthalmologists receive about a third of their cataract surgery patients as referrals from optometrists.

The ophthalmologists in our sample who used optometrists for follow-up care compared to those who perform their own post-surgical care generally have fewer years in practice; perform a much higher percentage of their surgeries in ASC's; having a much higher percentage of their patients referred to them from an optometrist, 33 percent as compared to 7 percent; tend to follow their patients for a shorter time after surgery; perform a significantly greater number of cataract surgeries, resulting in a much higher annual payment from Medicare, that is, $1.9 million for those who allow optometrists to run the follow-up care versus $930 for those who don't.

We also sought to determine the extent of services performed by ophthalmologists when optometrists billed for follow-up surgical care. We found that 88 percent of the ophthalmologists personally examined all their patients prior to and the day following surgery to identify potential surgical complications. This even though they are on a split billing rate.

As I have previously stated, we found that in 97 percent of the cases the ophthalmologists in our sample billed and received the global fee payment. In only 3 percent of cases did the surgeon use the modifier indicating that the post-surgical follow-up care would be provided by another professional.

We discovered that a small percentage of optometrists also bill Medicare for payments even though the ophthalmologists had billed for and received the global fee. We believe that HCFA will resolve this problem administratively with the carriers.

In conclusion, Mr. Chairman, we anticipate that the rapid, almost explosive growth of these arrangements and the fact that we still have under review 60 eye care cases may represent a need for further legislation.

As you know, we have previously recommended requiring a mandatory second surgical opinion program for elective surgeries. We continue to believe that a second surgical opinion program is the best way to make beneficiaries more informed consumers of health care services.

We also strongly support the recent decision by HCFA to require the PRO's to certify the need for all cataract surgeries prior to surgery, although such certification lacks consumer education benefits of second surgical opinions.

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[1] See appendix 6, p. 279.

The Office of the Inspector General is concerned that Medicare is indeed vulnerable to abusive referral arrangements. The recent identification of local physicians who have received kickbacks from laboratories clearly illustrates how vast these referral networks can be, and how easily abused.

Finally, I would like to emphasize that although we believe that overpayments identified in our study should be recovered through administrative actions, we would view a pattern of such behavior as a submission of false claims, subject to prosecution.

The Medicare and Medicaid Patient and Program Protection Act of 1987 to which we're indebted to your leadership, Mr. Chairman, gives us expanded authorities to deal with cases such as these. We will continue our efforts to prosecute, exclude and sanction health care professionals who attempt to defraud the Medicare and Medicaid programs.

Thank you.

[The prepared statement of Mr. Mitchell follows:]

TESTIMONY
OF
BRYAN MITCHELL
DEPUTY INSPECTOR GENERAL
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
SPECIAL COMMITTEE ON AGING
ON
OPTOMETRY - OPHTHALMOLOGY REFERRAL ARRANGEMENTS
MAY 23, 1988

GOOD MORNING, MR. CHAIRMAN AND MEMBERS OF THE SPECIAL COMMITTEE ON AGING. I AM BRYAN MITCHELL, ACTING DEPUTY INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES. I AM HERE THIS MORNING AT YOUR REQUEST TO SHARE THE PRELIMINARY RESULTS OF OUR CURRENT STUDY ON CATARACT SURGERY. HOWEVER, BEFORE ELABORATING ON THE FINDINGS OF THAT STUDY, I WOULD LIKE TO PROVIDE THE COMMITTEE WITH SOME BACKGROUND ON THIS ISSUE AND THE EXTENT OF OUR INVOLVEMENT IN THIS AREA.

BACKGROUND

CATARACT SURGERY IS THE PROCEDURE MOST FREQUENTLY PERFORMED ON THE MEDICARE POPULATION IN THE UNITED STATES TODAY. ABOUT 1.3 MILLION AMERICANS WILL HAVE A CATARACT REMOVED THIS YEAR.

HISTORICALLY, CATARACT SURGERY WAS PERFORMED IN AN INPATIENT HOSPITAL SETTING. SURGERY TOOK AS LONG AS 2 HOURS AND USUALLY WAS PERFORMED UNDER GENERAL ANESTHESIA. HOSPITAL STAYS OF UP TO 7 DAYS WERE USUALLY THE RULE, BUT THAT LENGTH

OF STAY HAS BEEN GREATLY REDUCED, AND TODAY MOST CATARACT SURGERIES ARE PERFORMED IN AN AMBULATORY SETTING.

IN 1985, THE OFFICE OF INSPECTOR GENERAL TESTIFIED BEFORE THE HOUSE SELECT COMMITTEE ON AGING ON FRAUD, WASTE AND ABUSE IN THE FIELD OF CATARACT SURGERY. AT THAT HEARING, WE PRESENTED OUR REPORT ON MEDICARE CATARACT IMPLANT SURGERY.

THE STUDY PRESENTED AT THAT HEARING WAS PART OF OUR INCREASING INVOLVEMENT IN EYE CARE ISSUES. IN ADDITION TO INSPECTIONS OF POLICY ISSUES, WE HAVE INVESTIGATED CASES WHERE MEDICARE WAS BILLED FOR SERVICES NOT RENDERED; OR BILLED FOR SERVICES AFTER THE SURGEON HAD BEEN EXCLUDED FROM THE MEDICARE AND MEDICAID PROGRAM; OR IN CASES WHERE THE SURGEON BILLED MEDICARE FOR MORE EXPENSIVE SERVICES THAN PROVIDED.

LET ME HIGHLIGHT FOR YOU SOME OF OUR CASES.

AN OPHTHALMOLOGIST BILLED THE MEDICARE PROGRAM FOR A SURGICAL LASER PROCEDURE CALLED ARGON LASER TRABECULOPLASTY (ALT), WHICH HE DID NOT PERFORM, OR DID NOT PERFORM IN ACCORDANCE WITH ACCEPTABLE MEDICAL PRACTICE. THE ALT PROCEDURE IS USED TO TREAT ADVANCED GLAUCOMA. SOME OF THE PATIENTS HE TREATED WERE NOT SHOWN TO HAVE ADVANCED GLAUCOMA; OTHERS DENIED HAVING THE EYE NUMBED AND A REFRACTORY LENS PLACED ON IT, WHICH IS A CRITICAL PART OF THE PROCEDURE.

IN ANOTHER CASE, A RETAIL EYEWEAR CORPORATION THAT LEASED

SPACE AT A CHAIN OF DEPARTMENT STORES, AND THE 4 INDIVIDUALS WHO RAN THE COMPANY, BILLED THE MEDICARE PROGRAM FOR:

- EYEWEAR NOT PROVIDED;
- EYEWEAR PROVIDED TO MEDICARE BENEFICIARIES WHO DID NOT HAVE CATARACT SURGERY;
- CATARACT EYEWEAR WHICH WAS NOT COVERED BY THE MEDICARE PROGRAM;
- EYEWEAR THAT WAS NOT MEDICALLY NECESSARY;
- EYEWEAR PROVIDED TO SOMEONE OTHER THAN THE MEDICARE BENEFICIARY.

WE ALSO INVESTIGATED AN OPHTHALMOLOGIST WHO HAD BEEN EXCLUDED FROM THE MEDICARE AND MEDICAID PROGRAM, BUT CONTINUED TO BILL THE FEDERAL HEALTH PROGRAMS USING ANOTHER PHYSICIAN'S PROVIDER NUMBER. IN ANOTHER CASE WE INVESTIGATED AN OPTOMETRIST WHO SUBMITTED FALSE MEDICARE AND MEDICAID CLAIMS FOR SERVICES, SUCH AS BILLING FOR BIFOCALS WHEN A SINGLE VISION LENS WAS PROVIDED.

AN OPHTHALMOLOGIST BILLED MEDICARE FOR ARGON LASER PHOTOCOAGULATION (LASER SURGERY) DURING A PERIOD OF TIME WHEN THE OPHTHALMOLOGIST DID NOT HAVE A LASER MACHINE IN HIS OFFICE. THE MACHINE HAD BEEN CONFISCATED BY THE U.S. MARSHALL, AND WAS STORED UNDER THE SUPERVISION OF THE MARSHALL'S OFFICE DURING THE PERIOD OF TIME THAT THE DOCTOR BILLED FOR SERVICES REPORTED TO BE PROVIDED WITH THE MACHINE. THE DOCTOR PLED GUILTY AND WAS SENTENCED TO THREE YEARS PROBATION.

FINALLY, I WOULD LIKE TO CITE THE CASE OF AN OPHTHALMOLOGIST FOUND TO BE SUBMITTING MEDICARE CLAIMS TO THE MEDICARE CARRIER FOR SERVICES RENDERED DURING THE PERIOD OF HIS LICENSE SUSPENSION. AT THE INFORMAL HEARING THE OPHTHALMOLOGIST TESTIFIED THAT HE HAD ISSUED PRESCRIPTIONS FOR CONTACT LENSES FOR APPROXIMATELY 60 PATIENTS FOR WHOM HE HAD NOT PERFORMED THE EYE EXAMINATION. HE ALSO TESTIFIED THAT THE OPTICIAN WHO EXAMINED THE PATIENTS PAID HIM $15 FOR EACH PRESCRIPTION. THE INVESTIGATION RESULTED IN GUILTY PLEAS BY BOTH THE OPHTHALMOLOGIST AND THE OPTICIAN.

OVERALL, 123 INVESTIGATIONS RELATED TO EYE CARE HAVE LED TO 17 CRIMINAL CONVICTIONS, THE EXCLUSION OF 50 EYE CARE PROFESSIONALS FROM MEDICARE PROGRAM PARTICIPATION, AND IMPOSITION OF $1.8 MILLION IN CIVIL MONETARY PENALTIES. THE PROVIDERS SANCTIONED OR FINED HAVE INCLUDED OPHTHALMOLOGISTS, OPTOMETRISTS, OPTICIANS, OPTICAL TECHNICIANS AND OPTICAL SUPPLY COMPANIES.

CITING THIS DATA, MR. CHAIRMAN, LAYS THE GROUND WORK FOR EXPLAINING WHY OUR OFFICE IS SO EXTENSIVELY INVOLVED IN THIS AREA AND WHY WE BELIEVE CONGRESSIONAL OVERSIGHT IS NECESSARY.

THE CATARACT SURGERY INDUSTRY IS ALREADY A MULTI-BILLION DOLLAR INDUSTRY. ACCORDING TO BILLING DATA MAINTAINED BY THE HEALTH CARE FINANCING ADMINISTRATION (HCFA), IN 1985 SURGEONS

BILLED $1.2 BILLION OF WHICH MEDICARE ALLOWED $907 MILLION. IN 1986, MEDICARE'S ALLOWED AMOUNT FOR SURGEONS INCREASED TO $1.4 BILLION. TOTAL COSTS, INCLUDING PRE-OPERATIVE DIAGNOSTIC TESTS, ASSISTANTS AT SURGERY, AND FACILITY FEES, ARE $3-4 BILLION. WE HAVE FOUND FROM OUR STUDY, WHICH I WILL DISCUSS LATER, THAT THE AVERAGE SURGEON IN OUR SAMPLE WHO PERFORMED HIS OWN FOLLOW-UP CARE ANNUALLY RECEIVES $930,000 IN MEDICARE PAYMENTS; BUT AS OUR STUDY WILL SHOW, SURGEONS IN OUR SAMPLE WHO REFER PATIENTS BACK TO OPTOMETRISTS RECEIVE, ON AN AVERAGE, $1.9 MILLION ANNUALLY FROM MEDICARE, BECAUSE OF THEIR HIGHER VOLUME. THESE FIGURES MAY NOT BE REPRESENTATIVE OF ALL OPHTHALMOLOGISTS, BUT THEY DO INDICATE THAT CATARACT SURGERY IS A LUCRATIVE BUSINESS.

LEGISLATIVE HISTORY

AS A RESULT OF OUR EARLY WORK IN THIS AREA, THE OFFICE OF INSPECTOR GENERAL ALSO TESTIFIED IN 1985 BEFORE THE HOUSE WAYS AND MEANS AND THE SENATE FINANCE COMMITTEE ON THE NEED FOR LEGISLATIVE CHANGES TO CURB EXCESSIVE MEDICARE PAYMENTS RELATED TO CATARACT SURGERY. WE ARE PLEASED THAT CONGRESS TOOK STRONG ACTION IN THE CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985 AND THE OMNIBUS BUDGET RECONCILIATION ACTS OF 1986 AND 1987 TO REDUCE CATARACT SURGERY FEES, LIMIT THE MARK-UP ON INTRAOCULAR LENSES, AND INSURE EQUALITY IN PAYMENTS FOR FEES PAID TO AMBULATORY SURGICAL CENTERS AND HOSPITALS.

FOR SEVERAL YEARS, OPTOMETRISTS HAVE BEEN PERMITTED TO BILL UNDER MEDICARE FOR SERVICES TO APHAKIC PATIENTS, THAT IS, PATIENTS WHO HAD A LENS REMOVED IN CATARACT SURGERY. THE COVERAGE OF SERVICES PROVIDED BY OPTOMETRISTS WAS FURTHER EXPANDED BY OBRA 1986 WHICH AUTHORIZED MEDICARE TO PAY OPTOMETRISTS DIRECTLY FOR ANY SERVICES THAT THEY ARE AUTHORIZED TO PERFORM UNDER THEIR RESPECTIVE STATE LAWS. DURING THE PERIOD 1980 THROUGH 1986, RELATIVELY FEW OPTOMETRISTS BILLED MEDICARE DIRECTLY FOR THE POST-OPERATIVE CARE OF THE PATIENT. HOWEVER, IT WAS COMMON IN CERTAIN AREAS OF THE COUNTRY FOR AN OPHTHALMOLOGIST WHO USED AN OPTOMETRIST'S SERVICES FOR POST-OPERATIVE CARE OF THE PATIENT TO BILL MEDICARE FOR THE FULL FEE FOR THE SURGERY AND THEN PAY THE OPTOMETRIST DIRECTLY FOR THE FOLLOW-UP SERVICES.

THE MEDICARE PROGRAM GENERALLY PAYS A "GLOBAL FEE" FOR CATARACT SURGERY. THAT GLOBAL FEE COVERS THE PRE-SURGICAL EVALUATION OF THE PATIENT, THE SURGERY ITSELF, AND THE POST-CATARACT SURGERY FOLLOW-UP VISITS. HCFA HAS ESTABLISHED A BILLING PROCEDURE WHICH ALLOWS FOR THE SPLITTING OF THE "GLOBAL FEE" BETWEEN THE OPHTHALMOLOGIST AND OPTOMETRIST, BY REQUIRING THE OPHTHALMOLOGIST TO PLACE A NUMBER "54" AT THE END OF THE SURGICAL PROCEDURE CODE. THIS MODIFIER "54", AS IT IS CALLED, IDENTIFIES FOR THE MEDICARE CARRIER THAT THE OPHTHALMOLOGIST IS NOT GOING TO PERFORM POST CATARACT SURGERY FOLLOW-UP VISITS. THE MEDICARE CARRIER REDUCES THE MEDICARE PAYMENT BY AN ESTABLISHED PERCENTAGE (RANGING FROM 5 TO 30 PERCENT AT DIFFERENT CARRIERS) OF THE NORMAL GLOBAL FEE

PAYMENT, THE DIFFERENCE GOING TO THE OPTOMETRIST WHO DOES PERFORM THE FOLLOW-UP VISITS AND WHO NOTIFIES THE CARRIER OF A REQUEST FOR PAYMENT BY USING THE RELATED MODIFIER "55".

CURRENT STUDY: SCOPE AND METHODOLOGY

AS A RESULT OF OUR EARLIER REPORTS AND OUR INCREASING NUMBER OF INVESTIGATIONS, AS WELL AS A REQUEST FROM HCFA, WE DECIDED TO UNDERTAKE ANOTHER STUDY. OUR STUDY WAS DESIGNED TO EXAMINE THE REFERRAL ARRANGEMENTS THAT ALLOWED FOR POST-OPERATIVE CATARACT CARE BY OPTOMETRISTS. WE FOCUSSED ON THE FREQUENCY OF SUCH ARRANGEMENTS, THE POTENTIAL IMPACT OF THIS PRACTICE ON THE PATIENT AND THE MEDICARE PROGRAM, THE REIMBURSEMENT IMPLICATIONS AND THE POTENTIAL FOR FRAUD AND ABUSE.

WE RANDOMLY SELECTED AND EXAMINED THE PAYMENTS MADE ON BEHALF OF 1,000 MEDICARE BENEFICIARIES IN 8 LOCALITIES. WE ALSO INTERVIEWED 58 OPHTHALMOLOGISTS, 28 OPTOMETRISTS AND 49 PATIENTS FROM THE SAME AREAS. ONE-HALF OF THE OPHTHALMOLOGISTS WERE SELECTED FROM AMONG THE HIGHEST PAID PROVIDERS AT THE RESPECTIVE CARRIERS AND THE OTHER HALF FROM THE MID-RANGE OF THE SPECIALTY. EACH CARRIER SAID THAT IT KNEW OF THE MODIFIER PROVISION AND HAD NOTIFIED THE VARIOUS OPHTHALMOLOGISTS AND OPTOMETRISTS IN ITS AREA.

PRELIMINARY FINDINGS

OUR REPORT HAS NOT BEEN COMPLETED; HOWEVER, BASED ON OUR ANALYSIS OF DATA TO DATE, WE HAVE DERIVED SOME PRELIMINARY FINDINGS. WE FEEL CONFIDENT THAT THE MAJORITY OF THEM WILL REMAIN AS DRAFTED WHEN WE ISSUE OUR REPORT. IN ADDITION, WITH YOUR PERMISSION, WE WILL BE PLEASED TO SUBMIT A COPY OF THAT REPORT FOR THE RECORD AS SOON AS IT IS COMPLETED.

BASED ON OUR ANALYSIS, WE HAVE FOUND THAT:

o IN 97% OF THE CASES WE REVIEWED THE OPHTHALMOLOGISTS BILLED MEDICARE A GLOBAL FEE FOR CATARACT SURGERY. THE MODIFIER (SPLIT BILLING) WAS USED ONLY IN 3% OF THE CASES.

o HOWEVER, 28% OF THE OPHTHALMOLOGISTS INTERVIEWED PERMIT OPTOMETRISTS TO PERFORM POST-OPERATIVE CARE. THESE OPHTHALMOLOGISTS RECEIVE ABOUT A THIRD OF THEIR CATARACT SURGERY PATIENTS AS REFERRALS FROM OPTOMETRISTS.

o THE OPHTHALMOLOGISTS IN OUR SAMPLE WHO USE OPTOMETRISTS FOR FOLLOW-UP CARE, COMPARED TO THOSE WHO PERFORM THEIR OWN POST SURGICAL CARE, GENERALLY:

  - HAVE FEWER YEARS IN PRACTICE;
  - PERFORM A MUCH HIGHER PERCENTAGE OF THEIR SURGERIES IN AN AMBULATORY SURGICAL CENTER;
  - HAVE A MUCH HIGHER PERCENTAGE OF THEIR PATIENTS

REFERRED TO THEM FROM AN OPTOMETRIST (33% COMPARED TO 7%);

- TEND TO FOLLOW THEIR PATIENTS FOR A SHORTER TIME AFTER SURGERY;
- PERFORM A SIGNIFICANTLY GREATER NUMBER OF CATARACT SURGERIES, RESULTING IN A MUCH HIGHER ANNUAL PAYMENT FROM MEDICARE, NAMELY, $1.9 MILLION FOR THOSE WHO ALLOW OPTOMETRISTS TO RENDER FOLLOW-UP CARE VS. $930,000 FOR THOSE WHO DON'T.

WE ALSO SOUGHT TO DETERMINE THE EXTENT OF SERVICES PERFORMED BY OPHTHALMOLOGISTS WHEN OPTOMETRISTS BILLED FOR FOLLOW-UP SURGICAL CARE. WE FOUND THAT 88% OF THE OPHTHALMOLOGISTS PERSONALLY EXAMINE ALL OF THEIR PATIENTS PRIOR TO AND THE DAY FOLLOWING SURGERY TO IDENTIFY POTENTIAL SURGICAL COMPLICATIONS.

AS I HAVE PREVIOUSLY STATED, WE FOUND THAT IN 97% OF THE CASES, THE OPHTHALMOLOGISTS IN OUR SAMPLE BILLED AND RECEIVED THE GLOBAL FEE PAYMENT. IN ONLY 3% OF CASES DID THE SURGEON USE THE MODIFIER INDICATING THAT THE POST-SURGICAL FOLLOW-UP CARE WOULD BE PROVIDED BY ANOTHER PROFESSIONAL.

HOWEVER, IN REVIEWING THESE CASES, WE DISCOVERED THAT A SMALL PERCENTAGE OF OPTOMETRISTS ALSO BILLED MEDICARE FOR PAYMENT EVEN THOUGH THE OPHTHALMOLOGIST HAD BILLED FOR AND RECEIVED A GLOBAL FEE PAYMENT. OUR REPORT WILL RECOMMEND THAT HCFA RESOLVE THIS PROBLEM ADMINISTRATIVELY AND HAVE THE CARRIERS

PUT IN PLACE THE NECESSARY SCREENS TO CATCH THIS IN THE FUTURE. HOWEVER, MR. CHAIRMAN, WE ARE CONCERNED THAT THIS PROBLEM COULD BE JUST THE TIP OF THE ICEBERG. IF WE FIND THAT THERE IS A PATTERN TO THIS PRACTICE, WE WILL CONSIDER THESE OVERPAYMENTS AS POTENTIALLY FALSE CLAIMS, PROSECUTABLE BOTH CIVILLY AND CRIMINALLY.

CONCLUSION

IN CONCLUSION, WE ANTICIPATE THAT THE RAPID GROWTH OF THESE ARRANGEMENTS, AND THE FACT THAT WE STILL HAVE UNDER REVIEW 60 EYE CARE CASES, MAY REPRESENT A NEED FOR FURTHER LEGISLATION. AS YOU KNOW, WE HAVE PREVIOUSLY RECOMMENDED THAT LEGISLATION BE ADOPTED TO REQUIRE A MANDATORY SECOND SURGICAL OPINION PROGRAM FOR ELECTIVE SURGERIES, SUCH AS THESE, PAID UNDER MEDICARE. WE CONTINUE TO BELIEVE THAT A SECOND SURGICAL OPINION PROGRAM IS THE BEST WAY TO MAKE BENEFICIARIES MORE INFORMED CONSUMERS OF HEALTH CARE SERVICES.

WE ALSO STRONGLY SUPPORT THE RECENT DECISION BY HCFA TO REQUIRE PROS TO CERTIFY THE NEED FOR ALL CATARACT SURGERIES PRIOR TO THE SURGERY. WE EXPECT THIS REVIEW IN THE OUTPATIENT SETTING TO BE A VALUABLE TOOL TO REDUCE UNNECESSARY SURGERY, ALTHOUGH SUCH CERTIFICATION LACKS THE CONSUMER EDUCATION BENEFITS OF SECOND SURGICAL OPINIONS.

THE OIG IS CONCERNED THAT MEDICARE IS INDEED VULNERABLE TO ABUSIVE REFERRAL ARRANGEMENTS. THE RECENT MEDIA COVERAGE OF THE IDENTIFICATION OF LOCAL DOCTORS WHO HAVE RECEIVED

KICKBACKS FROM LABORATORIES CLEARLY ILLUSTRATES HOW VAST THESE REFERRAL NETWORKS CAN BE, AND HOW EASILY ABUSED. WE SHARE YOUR CONCERN AT THE RAPID GROWTH OF SUCH ILLEGAL NETWORKS. WE WILL CONTINUE TO PURSUE CRIMINAL AND CIVIL REMEDIES AGAINST THEM.

FINALLY, I WOULD LIKE TO EMPHASIZE THAT ALTHOUGH WE BELIEVE THE OVERPAYMENTS IDENTIFIED IN OUR STUDY SHOULD BE RECOUPED AND THE PROVIDERS EDUCATED, WE WOULD VIEW A PATTERN OF SUCH BEHAVIOR AS THE SUBMISSION OF FALSE CLAIMS, SUBJECT TO PROSECUTION. THE MEDICARE/MEDICAID PATIENT AND PROGRAM PROTECTION ACT OF 1987, PUBLIC LAW 100-93, GIVES US EXPANDED AUTHORITIES TO DEAL WITH CASES SUCH AS THESE. WE WILL CONTINUE OUR EFFORTS TO PROSECUTE, EXCLUDE AND SANCTION HEALTH CARE PROFESSIONALS WHO ATTEMPT TO DEFRAUD THE MEDICARE AND MEDICAID PROGRAMS.

MR. CHAIRMAN, THIS CONCLUDES MY TESTIMONY. I WOULD BE PLEASED TO ANSWER ANY QUESTIONS YOU MAY HAVE.

Senator HEINZ. Mr. Mitchell, thank you very much. I'll have questions for you but we'll go and hear from each member of the panel in sequence.

So I'd like to welcome Doctor Stokes. Doctor Stokes, please proceed.

STATEMENT OF HUNTER STOKES, M.D., SECRETARY FOR GOVERNMENT RELATIONS, AMERICAN ACADEMY OF OPHTHALMOLOGY, WASHINGTON, DC

Dr. STOKES. Thank you, Senator Heinz.

My name is Hunter Stokes, I'm an ophthalmologist in private practice in Florence, South Carolina, and serve as Secretary for Government Relations of the American Academy of Ophthalmology representing more than 96 percent of the ophthalmologists in the country.

I trained here in Philadelphia at Will's as did both my brothers in my practice. I have a son who starts here next month so, though I don't sound like a native Philadelphian, I appreciate the opportunity to be back here. At least I consider this to be my second home.

We're here today to discuss with this committee a practice by a small but growing number of physicians which is jeopardizing the quality of medical eye care in this country, and, I fear, it is tarnishing the reputation of my medical speciality. It's a practice that raises serious ethical and possibly legal questions.

The Academy is doing everything it can to maintain the high medical and ethical standards of the great majority of our members, and to discourage and condemn those few which choose to violate the trust of our patients.

The financial rewards to abrogate care of post-operative patients to optometrists is tempting, but the overwhelming majority of our members insist on taking care of their patients from the pre-operative work-up through the post-operative period. It's only a small minority who object to our stand who wish to maximize their profits.

One of our chief concerns is HCFA's broad interpretation of the recent legislation which for the first time enables optometrists to separately bill Medicare for their services.

We're not here to advocate the repeal of that legislation, but to limit the scope of its interpretation. Since we don't think that providing optometric care in the post-operative period should be a part of the Medicare reimbursements.

HCFA's 1987 guidelines have encouraged and reinforced referral patterns that lead to an increase in premature and perhaps indeed unnecessary cataract surgery and inadequate treatment of post-operative complications, certainly has heard it from the ladies in the first panel, by supporting economic incentives to refer patients to elective surgeons who will return the patients immediately after.

No other surgical procedure is splintered between care and physicians and non-physicians for financial interest.

We're concerned because the post-operative period represents the time of highest risk to the patient for complications. Although cataract surgery enjoys a relatively low rate of serious complications, there are complications that can result in decreased vision. They occur in about 5 percent of cataract patients.

Even with these complications cataract surgery is very successful. Because at the present time the complications are recognized and managed immediately by the people who are best prepared to manage it, the surgeon.

Despite claims by optometrists that they can treat patients, they do not have the training to determine the implications of various post-op conditions such as the level of swelling, bleeding, pain, pressure, and the reaction to medications nor the appropriate treatment.

For example, here's a quick list of typical complications and the frequency with which they're likely to occur in the hands of a general ophthalmologist.

Elevated pressure after surgery, 1 out of 10. Retinal edema, 1 out of 10. Iritis, or inflammation in the eye, 1 out of 20. Hemorrhage inside the eye, 1 out of 50. Retinal detachment, 1 out of 100. Dislocation of the implanted intraocular lens, 1 out of 500. And significant infection, serious infection, or stitch breakage, 1 out of 2,000.

While pain, redness and swelling may be detected by the patient, another family member, a nurse or an optometrist, only the operating surgeon or medical doctor of similar competence and experience can accurately diagnose the cause and significance, and determine the treatment of these and other possible post-operative complications.

Optometric licensing and training does not provide background knowledge, working experience nor scope of practice to certify an optometrist to perform key diagnostic and treatment services for the post-op patient.

States have not granted optometrists permission or license to practice post-op care. The 1986 law extended Medicare coverage to services for which optometrists are licensed by their States to provide. Congress referred to services, not treatment.

States do not license optometrists to perform surgical care; only medical doctors, licensed by State boards of medical licensure, and granted specific privileges by hospitals, are permitted to practice medicine and surgery. Post-op care of a patient is a part of the medical license. In no State does the Optometric Practice Act specifically permit the treatment of post-op patients.

Because we sense that HCFA believes it is interpreting the law according to Congressional intent, we're coming to you today to request that Congress give more explicit direction to HCFA.

Specifically, we urge you to prohibit the unbundling of the global fee for cataract surgery, and prohibit the use of the modifier. This is the way other procedures are handled under Medicare. Non-physicians do not provide or bill for post-operative services under Medicare for any other operation.

And second, we would hope you might require the referring Medicare provider, the non-surgeon, to disclose any financial relationships they have with the operating surgeon.

Senator, last month Aloha Airlines had a short inter-island hop on a reliable airline, a relatively insignificant flight, but it took all the skills and experience of a very well trained and experienced set of pilots to bring that plane down with minimal damage.

At no additional cost to the Medicare Program and, we believe, actually at a savings, Congress has the opportunity, we think, to assure senior citizens of our country that the very best person will be in the pilot seat before, during, and after cataract surgery.

Thank you very much for the opportunity to speak.

[The prepared statement of Dr. Stokes follows:]

STATEMENT OF THE
AMERICAN ACADEMY OF OPHTHALMOLOGY
TO THE
SPECIAL COMMITTEE ON AGING
U.S. SENATE

FIELD HEARINGS ON THE
MEDICARE REIMBURSEMENT OF POST-OPERATIVE SERVICES
FOLLOWING CATARACT SURGERY

MAY 23, 1988

PHILADELPHIA, PENNSYLVANIA

My name is Hunter Stokes. I am an ophthalmologist in private practice in Florence, South Carolina, and the Secretary for Representation for the American Academy of Ophthalmology, representing more than 16,000 or 96% of the ophthalmologists in the country.

We are here today to discuss with this Committee a practice by a small but growing number of physicians, which is jeopardizing the quality of medical eye care in this country, and, I fear, is tarnishing the reputation of my medical specialty. It is a practice that raises serious ethical and possibly legal questions.

The Academy is doing everything it can to maintain the high medical and ethical standards of the great majority of our members, and to discourage, and condemn those few who choose to violate the trust of our patients. We are taking these actions because just six months ago, our members, through the deliberative process of our representative Council, directed the Academy's Board of Directors to make every effort to prevent the erosion of care during the post-operative period.

The financial rewards to abrogate care of post-operative patients to optometrists are tempting, but the overwhelming majority of our members insist on taking care of their patients from the pre-operative work-up through the post-operative recovery period. It is only a very small minority who object to our stand -- and who wish to maximize their profits at the patient's expense. The antitrust laws, and the narrow range of sanctions available to us as a private membership organization limit our power to impose standards of patient care and the ethical norms embraced by most ophthalmologists on the small minority of our members who do not accept them. That is why we must appeal to Congress to help us in this effort.

One of our chief concerns is HCFA's broad interpretation of the recent optometric reimbursement legislation, which for the first time enables optometrists to separately bill Medicare for providing services. We are not here to advocate the repeal of this legislation, but to limit the scope of its interpretation, since we do not think that providing optometric care during the post-operative period should be covered under Medicare.

In its efforts to control duplicate billing by the surgeon and the optometrist during the post-operative period, HCFA has allowed the unbundling of the global fee and unwittingly stimulated the marketing of cataract patients. This new policy sets a precedent that could have serious effects not only on the quality of eye care, but if permitted to continue could have significant ramifications for the delivery of other medical services, far beyond ophthalmology.

We address this Committee today because the great majority of our members are outraged by what present Medicare practices have encouraged: the abandonment of the cataract patient before the post-operative recovery period has been completed, and while the patient is most susceptible to numerous medical complications; financially driven referral arrangements; unnecessary surgery; and betrayal of the principle of informed consent in a vulnerable patient population comprised largely of senior citizens.

HCFA's 1987 guidelines on the optometric expansion -- aimed at preventing duplicate payment -- have encouraged and reinforced referral patterns that lead to an increase in pre-mature or indeed unnecessary cataract surgery and inadequate treatment of post-operative complications, by supporting economic incentives to refer patients to selected surgeons who will return the patient immediately following surgery for post-operative care. In many areas, we believe that HCFA has forced local Medicare insurance carriers to act contrary to state practice and law to adopt the national guidelines, even in states where optometrists do not have the authority to use the medications that are commonly prescribed following cataract surgery.

There is evidence that such economic incentives are so strong that new forms of aggressive promotion are growing, aimed exclusively at the marketing of Medicare patients to have cataract surgery. Sometimes, this results in the elderly patient traveling great distances, perhaps into another state, for care from the referral network. In most cases, the patient is almost certainly unaware of any financial arrangement existing between the referring provider and the operating surgeon. In some cases, perhaps in a significant portion, the cataract surgery may be performed without an adequate pre-operative examination by the surgeon, and possibly without a full understanding of the patient's need or desire to have the surgery.

"In the past, an independent professional optometrist served as a check and balance for a potential overly aggressive surgeon who might perform unnecessary surgery based on questionable indications. Today...the optometrist now obtains a part of the surgeon's fee and ... the optometrist and surgeon now both benefit from overutilization of the system." This is a quote from a Pennsylvania ophthalmology group in a letter to their Medicare carrier, protesting the new interpretation. To quote again:

"Our group practice has already been bombarded by such requests from optometrists eager to cash in on this financial bonanza. The implications to those of us who feel the patient is not best served by this approach is certainly clear. No sign off [from the global fee], no referrals.... Since large numbers of surgical patients are optometric referred, ophthalmologist participation in this program is essentially coercive out of fear of boycott."

No other surgical procedure is splintered between care by physicians and non-physicians for financial interests. Indeed, government policy makers, including HCFA officials, are developing plans for enhancing and defining global fees. As surgeons, we have been accustomed to charging for our surgical procedures under a global fee that generally includes a significant post-operative recovery period.

We are concerned because the post-operative period represents the time of highest risk to the patient for complications which are best treated by the operating surgeon who was intimately aware of the unique characteristics of the operative eye and the immediate effects of his surgery. Although cataract surgery enjoys a relatively low rate of serious complications, there are many complications that can result in decreased vision, or aggravate the patient's other existing medical conditions. While complications may occur in about 5% of cataract patients, when one considers that the yearly volume is more than 1 million, the number who suffer complications is significant -- perhaps as high as 40,000 to 50,000 patients per year.

Despite claims by optometrists that they can "treat" patients, they do not have the training to determine the implications of various post-operative conditions, such as the level of swelling, bleeding, pain, increased ocular pressure, and reaction to medications, nor the appropriate treatment.

For example, here is a list of the typical complications and the frequency they are likely to occur, based on 150-200 cataract operations per year (2-4 per week). Tertiary centers and certain subspecialists (corneal or retinal surgeons) may encounter a higher rate of certain complications because they may accept a higher risk patient. These figures are based on our best estimation, and do not necessarily reflect statistical norms.

1. Significant elevation of the pressure in the eye, which the surgeon deems to be high enough to require oral or topical medication: 1 out of 10 cases.

2. Retinal edema (swelling): 1 out of 10 cases. Depending on the surgeon's judgement of its significance, it will be treated with steroids and/or other medication.

3. Iritis (excessive inflamation inside the eye): 1 out of 20 cases. Depending on the surgeon's diagnosis of its cause, it will usually be treated with medicated drops.

4. Hemorrhaging inside the eye, detected with a slit lamp examination: 1 out of 50 cases. Depending on the surgeon's diagnosis of its source and judgement of its significance, the surgeon might treat it with bed rest, if it is a minor problem, or may be required to reoperate.

5. Retinal detachment: 1 out of 100 cases. This will require immediate surgery to attempt to reattach the retina. Time is of the essence here. Loss of vision could result.

6. Dislocation of the implanted intraocular lens (IOL): 1 out of 500 cases. The decision to reoperate to relocate, replace or remove the IOL will depend on the surgeon's diagnostic judgement of how significant the dislocation, how much tissue destruction and/or visual distortion.

7. Significant infection and stitch breakage: 1 out of 2,000.

While pain, redness, and swelling may be detected by the patient, nurse, family member or optometrist, only the operating surgeon or a medical doctor of similar competence and experience can accurately diagnose the cause and significance, and determine the treatment of these and other possible post-operative complications.

Optometric licensing and training do not provide the background knowledge, working experience nor scope of practice to certify an optometrist to perform key diagnostic and treatment services to post-operative patients.

For example, I recently heard from an ophthalmology resident, who had trained as an optometrist, in 1979, before he decided to go, and was accepted into medical school. He said that in his four years of optometry training, he saw about a dozen cases of eye disease. Today, in his ophthalmological residency, he sees in one day more pathology than during his whole optometric experience. As a medical resident, he sees real human beings, who come to him with their own unique complexities of ocular and systemic complications, not just slides, lectures, or textbook cases. We are happy to submit for the record, testimony presented to the

Pennsylvania state legislature that provides detailed descriptions of the differences between optometric and ophthalmological training.

One reason the training is so different, is that optometric services are geared toward the healthy eye, the healthy patient who needs corrective lenses to read or drive. A medical doctor's training is just the opposite: geared toward acute and chronic diseases affecting the eye and other functions and organs of the whole person.

In a number of states, optometrists have won, through political means, state permission to prescribe a limited list of medications, some of which I would use in my treatment of post-operative patients. However, this does not mean that the states have granted optometrists the permission or license to practice post-operative care. I learned to treat patients, judiciously using topical and systemic medications, through years of medical school, residency, specialty training in ophthalmology and continuing medical education. In states where optometrists are permitted to prescribe some drugs, they take lectures and read textbooks about the chemical make-up of the drugs. This is not sufficient training to treat surgical patients.

In 1980, when legislation was first enacted to allow optometrists to bill Medicare for "aphakia" services -- services to patients who had had their cataract lens removed -- there was lengthy discussion among the lawmakers regarding the appropriate terminology to describe the expansion of coverage. At that time, Congress agreed that they were not handing the medical management of the post-surgical patient to a non-physician, but that cataract patients, once released by the operating surgeon, could receive services from optometrists under Medicare. Congress was very exact in its wording of the law, saying that the coverage was for "services related to the condition of aphakia" (absence of the natural lens), not for the treatment of aphakia.

Indeed, in the further expansion, which we note the Administration opposed, the 1986 law extends Medicare coverage to "services for which optometrists are licensed by their states to provide." Again, Congress refers to services, not treatment. States do not license optometrists to perform surgical care; only M.D.s, licensed by state boards of medical license, and granted specific privileges by hospitals are permitted to practice medicine and surgery. Post-operative care of a patient is part of the medical license. In no state does the optometric practice act specifically permit the treatment of post-operative patients.

Finally, we wish to make it clear that we have attempted to work with HCFA on the issue of financially driven referral networks and unbundling of the global fee. Last year, as Peer Review Organizations were gearing up for the second opinion program, which has not yet been implemented, we developed pre-approval guidelines with the PRO's assistance, that allowed individual PROs to disapprove the surgery unless the post-operative management remained the responsibility of the operating surgeon.

HCFA rejected these guidelines, saying that provision of post-operative care could not be a prerequisite for pre-surgical approval, since it could only be verified after the surgery took place. We objected to this interpretation on the grounds that HCFA again appeared to be condoning questionable referral practices, at least in a passive way; and that the PROs -- who said that they could use this as a guideline -- should have been allowed the latitude to develop such a guideline. This occurred despite the insistence by HCFA that PRO guidelines were to be aimed at guaranteeing the quality of care. By allowing the networking of referrals for financial gain between optometrists and ophthalmologists, HCFA is compromising its standards of quality.

Because we sense that HCFA believes it is interpreting the law according to Congressional intent, we are coming to you today, to request that Congress give more explicit direction to HCFA. Specifically, we urge you to:

(1) Prohibit the unbundling of the global fee for cataract surgery, and prohibit the use of the modifier when the operating surgeon or a surgeon of similar competence does not provide the post-operative care. This is the way other procedures are handled under Medicare. Non-physicians do not provide or bill for post-operative services under Medicare for any other operation. And,

(2) Require the referring Medicare providers to disclose any financial relationships they have with the operating surgeon.

Thank you for this opportunity to present our views.

AMERICAN ACADEMY OF OPHTHALMOLOGY

SECRETARIAT FOR
GOVERNMENTAL RELATIONS

Hunter R. Stokes, M.D.
Secretary
Post Office Box F-17
602 East Cheves Street
Florence, South Carolina 29501

Allan D. Jensen, M.D.
Associate Secretary for
Federal Economic Policy
14 West Mount Vernon Place
Baltimore, Maryland 21201

Michael A. Lemp M.D.
Associate Secretary for
Research, Regulatory Agencies
and Federal Systems
Center for Sight
Georgetown University Medical Center
3800 Reservoir Road, N.W.
Washington, D.C. 20007

David W. Parke, M.D.
Associate Secretary for
State Affairs
477 South Broad Street
Meriden, Connecticut 06450

Arthur M. Reynolds Jr., M.D.
Associate Secretary for
Federal Legislation
1515 Chain Bridge Road
McLean, Virginia 22101

OFFICE OF
GOVERNMENTAL RELATIONS

Cynthia C. Root
Director
1101 Vermont Avenue, N.W.
Suite 300
Washington, D.C. 20005-3570
(202) 737-6662

FOR THE RECORD ONLY

ATTACHMENT TO THE

STATEMENT OF THE

AMERICAN ACADEMY OF OPHTHALMOLOGY

TO THE

SPECIAL COMMITTEE ON AGING

U.S. SENATE

FIELD HEARINGS ON THE

MEDICARE REIMBURSEMENT OF POST-OPERATIVE SERVICES

FOLLOWING CATARACT SURGERY

MAY 23, 1988

PHILADELPHIA, PENNSYLVANIA

TESTIMONY

Public Hearing of
The Senate Consumer Protection and Professional Licensure Committee
Regarding Senate Bill 657

August 26, 1987
Harrisburg, PA

Stephanie Jones Marioneaux, MD
Philadelphia, PA

My name is Stephanie Jones Marioneaux, MD and I am currently a senior resident at the Wills Eye Hospital.

My intent this morning, will be to speak to the issue of ophthalmic training and contrast it with that of optometry. I will be expounding on my experience, which would generally be considered representative of that for all ophthalmology residents and most practicing ophthalmologists.

I completed my undergraduate training in Biology at Harvard-Radcliffe University in Cambridge, Massachusetts and graduated Cum Laude. Following this, I spent 4 years at Harvard Medical School in Boston, where I received my M.D.

The first two years of medical school, are very intensive introductions to the basic medical sciences, as well as an introduction to the clinical aspects of patient care. Although selected courses may also comprise portions of the curriculum for other doctoral candidates, i.e. pharmacology and biology, medical education assumes a different emphasis the remaining two years. During this time we spend 80-90 hours a week in the hospital, directly involved in patient care. Most importantly, however, is the proficiency we developed in both the diagnosis and treatment of medical and surgical diseases; learning also the dangers and benefits of many therapeutic regimens.

At the completion of medical school, our level of competency in all aspects of diagnosis and treatment of medical and surgical diseases is rigorously tested by the National Board of Medical Examiners. Parts I, II and III of the National Medical Boards Examination are administered over 4 full, 8 hour days, or in several states, Parts I and II of the FLEX examination for two days. A designated percentage of graduates will fail each year, and as a result will be ineligible to practice medicine or dispense medications. Medical knowledge and proficiency are assessed and monitored on a national basis. No such equivalent mechanism for monitoring optometric claims of similar competency exists; i.e., a means by which they are examined by the same licensing boards as those physicians who have earned the privilige of dispensing medications.

After successfully graduating from medical school and passing the National Board Examinations, I completed a full year of medical internship at Mount Auburn Hospital in Cambridge, which is a Harvard affiliated program. During this time, I was the primary care physician for hundreds of patients in ambulatory, inpatient and emergency settings. At every step of the way, I was gaining invaluable experience in the practical application of all of the medical sciences. There is no equivalent training in optometry which provides for this kind of experience which is so fundamental to a thorough understanding of the specifics of therapeutics and how they relate to disease entities.

After internship, I was privileged to begin my three years of ophthalmology residency at the Wills Eye Hospital. Training in ophthalmology consists of an additional three years at an accredited institution such as Wills. Let me describe a typical day at Wills in order to better outline the nature of our training.

A typical day begins at 6:45 a.m. with 2 of our daily lecture series. In these lectures, diagnosis and treatment of ocular diseases are extensively reviewed. The general clinic begins immediately thereafter at 8:45 and ends when the last patient is seen at approximately 6:00 p.m. During that time, we each generally examine between 30 and 35 patients, the majority of whom requested refractions. Of these patients, 4 required referral to specialty clinics, 5 required special testing and one was scheduled for an immediate brain CAT SCAN. All of these patients had come for "routine eye examinations."

At the completion of my three years at Wills, I will have spent a total of 8 months in the General Ophthalmology Clinic, in addition to 3 to 4 additional months in all of the subspecialty departments such as glaucoma, retina and cornea; where often more serious diseases are encountered. I will also receive extensive surgical experience, as well as rotations in the primary care areas of pediatric ophthalmology and the Wills emergency room. Over 100 patients a day are often seen in the Wills emergency room, which is staffed by the residents under faculty supervision.

We are also responsible for general physical examinations, review of medical orders and consultations from other services at Jefferson Hospital. Exposure to such a plethora of eye conditions, which will probably exceed 5,000 patients, at the end of my residency, has heightened my ability to diagnose, treat and most importantly, recognize the potentially serious from the "routine."

In my review of previous testimony by optometrists, including the College of Optometry catalogs, most suggest that the best optometric education will include "800 patient experiences." Most of these are healthy eyes in healthy people. Patients previously seen at the Optometric Eye Institute in Philadelphia are frequently seen and subsequently managed at Wills.

Ophthalmology and optometry training seem to be unfair comparisons. Ophthalmologists will spend 8-10 years learning to diagnose disease and master the intricacies of therapeutics. Optometric training can in no way provide a comparable level of expertise, particularly in the setting of the ever expanding fund of medical knowledge.

In summary, training in Ophthalmology provides both specialized and basic eye care. There is an emphasis on basic eye examinations and treatment as most ophthalmologists spend the majority of their time doing routine exams, functioning as the "front line" in eye care.

TESTIMONY

Public Hearing of
The Senate Consumer Protection and Professional Licensure Committee
Regarding Senate Bill 657

August 26, 1987
Harrisburg, PA

Drew J. Stoken, MD
Carlisle, PA

My name is Drew Stoken. I am a Medical Doctor and I have recently finished my ophthalmology residency. I'm here now to share with you my unique viewpoint concerning ophthalmologists and optometrists. A close relative of mine has also recently finished training - as an optometrist - at the Pennsylvania College of Optometry (PCO). We've followed each other closely throughout our training and through this I have become acquainted with many optometrists.

I'm speaking to you today because I believe allowing optometrists to treat eye diseases is a serious mistake - placing not only the public but optometrists as well in grave danger. I am here to present facts to allow you to put into perspective the different levels of training between the optometrist and the ophthalmologist.

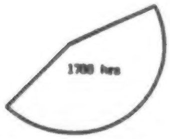
Optometrists compare their training with other practitioners such as family practitioners, pediatricians, dentists and others and claim that their training is to provide "primary eye care" which includes treating "uncomplicated diseases."

Let's look at the facts. It's true that some optometry school lecturers also teach in medical schools, but they also teach nurses and technicians, however, the courses are in no way comparable.

Let's compare curriculae. My figures are taken from the 1984-86 PCO Catalogue and the 1984-85 Jefferson Medical College Catalogue.

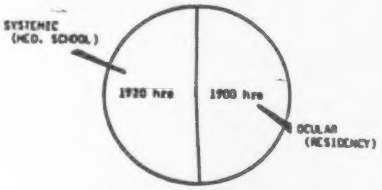
During the four years at PCO a student gets about 1700 hours of formal lecture[1] - and it true this is only slightly less than the 1920 hours[2] in the first two years of medical school, but let's not forget the 1900 hours of lecture in three years of residency[3].

This is depicted below in diagram 1 and 2.



CLASSROOM BASIC SCIENCES
PENNA. COLL. OF OPTOMETRY

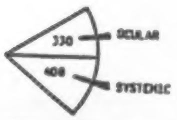
DIAGRAM 1



CLASSROOM BASIC SCIENCES
OPHTHALMOLOGIST' TRAINING

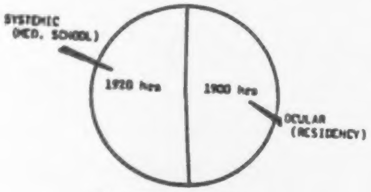
DIAGRAM 2

Now, let's "compare apples to apples" by removing the 960 hours out of that 1700 that are devoted strictly to refraction, optics, etc. This leaves about 738 nearly equally divided between the study of ocular and bodily (systemic) medicine. You see that over one half of their curriculum is devoted to "Optometrics." Knowing this, let's again show this in diagrams 3 and 4.



CLASSROOM BASIC SCIENCES
PENNA. COLL. OF OPTOMETRY

DIAGRAM 3



CLASSROOM BASIC SCIENCES
OPHTHALMOLOGIST' TRAINING

DIAGRAM 4

Let me point that this is as far as the study of systemic medicine goes. It's only classroom work with NO hands-on experience. Some refer to this as "cookbook medicine," which is at best inadequate. A good analogy would be flying an airplane after taking only classroom instruction.

My optometrist friends tell me, "We're taught systemic pharmacology, so we know all about drugs used throughout the body." PCO gives 30 hours in systemic pharmacology[1], compared to 164 hours at Jefferson Medical College[3], whereas nursing students get 46 hours[4]. You see that optometry students learn less systemic pharmacology than nurses, yet nurses aren't allowed to treat patients independently.

My optometrist friends often say, "We get lectures in clinical medicine, so we know about systemic diseases just like physicians do." PCO gives 30 hours[1] of lecture in clinical medicine compared to 800 hours[3] in medical school - not to mention our 3 full-time years of hands-on clinical bedside experience in medical school and internship. It is naive to dismiss the ophthalmologists' medical background as unnecessary for the practice of primary eye care - the eye is but a small part of a complex system...it's part of the brain, and as a physician I was trained to respect this.

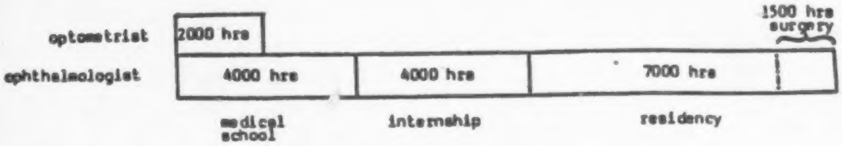
On the other hand, the optometrist is not required to build the foundation of knowledge that a physician has. Allow me to quote Donald Schwartz, MD - a physician who taught optometry students in California. "There is a vast body of knowledge and experience which a physician has and an optometrist doesn't. Because this knowledge is unknown to the optometrist, he doesn't realize that it exists, or even more important, that it may be crucial to treating disease. The optometrist simply does not know what he doesn't know."

Ask yourselves - is it safe for an optometrist to treat a "minor infection" in an eye, knowing that PCO doesn't even offer a course in microbiology?

Ophthalmology residency programs are referral centers for sick eyes, and seeing disease is a routine part of an ophthalmologist's training. On the other hand, the vast majority (by some estimates 98%[5]) of exams by optometry students are performed on healthy eyes. Optometry students don't see enough ocular disease to be able to tell simple from complicated problems. During my training I've see certain diseases, sometimes hundred of cases, the nature of which have never and will never be seen and appreciated by graduates of an optometry school.

Caring for disease is not a "9 to 5" job and as a resident I logged countless hours of night call in which I experienced the evolution and natural course of the disease process. This aspect is absent in optometric training. My lifestyle has not changed since I left my residency, and my wife claims that I am married to my beeper, however, this is an essential part of providing medical care. This aspect is also absent in the practice of optometry.

I would like to address one final point and this is the analogy of cardiologist to cardiac surgeon, neurologist to neurosurgeon and optometrist to ophthalmologist. I would like to point out that all of the specialties mentioned above have graduated from medical school, except the optometrist. Shown below is a breakdown of the clinical hours of training I have experienced in my eight years of medical school, internsip and residency. This is compared to the optometrist's experience[1].



The dotted line in the residency portion are the hours devoted to the operating room. I might also add that the average ophthalmologist in the U.S. performs around two operations per week. It should be very clear amounts to a small portion of the training and practice of an ophthalmologist.

In closing, optometrists and ophthalmologists have two different levels of training preparing graduates for two different levels of care. The graduates of optometry school are well qualified vision practitioners but are incapable of practicing medicine by virtue of their inadequate training. Allowing optometrists to practice medicine would harm the public, as well as the optometrist with the risk of serious malpractice.

Vision is indeed God's greatest gift - and it deserves the best possible care!

REFERENCES

1. PCO Catalogue 1984-1985
2. Jefferson Medical School Catalogue 1984-1985
3. University of Pittsburgh School of Nursing Catalogue 1984-1985
4. Optometric Monthly October, 1982

Senator HEINZ. Doctor Stokes, thank you very much.

Doctor Hanlen.

STATEMENT OF HARVEY HANLEN, O.D., CHAIRMAN, FEDERAL RELATIONS COMMITTEE, AMERICAN OPTOMETRIC ASSOCIATION, WASHINGTON, DC

Dr. HANLEN. Thank you, Senator Heinz.

I am Harvey Hanlen, a doctor of optometry in private practice in State College, Pennsylvania, and Chairman of the American Optometric Association, Federal Relations Committee.

I appreciate the opportunity to appear before you today to discuss the issue of reimbursement for cataract surgery and post-operative care under Medicare.

Let me state at the outset that your concerns are not taken lightly by our association. We have been pleased to cooperate with both the Office of Inspector General and the General Accounting Office in their studies into this issue.

I am pleased to address the issue of referrals for consultation and co-management between doctors of optometry and ophthalmologist and specifically some of the questions raised by the anecdotal reports which led to these investigations which have also been provided to your committee.

Optometry, according to HCFA, diagnose the large majority of developing cataracts in this country. Once the diagnosis is made, the doctor of optometry must determine the rate of development of the cataract, the degree to which it is affecting the patient's vision as well as visual health, explain the options to the patient and plan for the referring of the patient to an ophthalmic surgeon when surgery appears to be indicated.

The decision on where to refer a patient should be based on providing the best potential outcome for that patient; that is, restoration of vision to the optimum level possible with the least potential for complications. Thus, knowledge of the comparative skills and track records of surgeons can and does play an important role.

Let me state firmly that AOA believes referrals that are not based on this patient welfare criteria but instead are motivated solely on an economic agreement have no place in the system.

I would like to turn now to the specific issue of post-operative care for patients who have received cataract surgery. There are two points I would like to emphasize.

First, as substantiated by the Department of Health and Human Services study and recognized by an increasing number of ophthalmic surgeons, doctors of optometry are clinically trained and legally licensed to care for post-cataract patients, and diagnose complications that can result from this procedure.

Second, the decision to involve a doctor of optometry in post-operative care and to what degree rests with the surgeon, based on the professional relationship between the two providers, and following a post-surgical evaluation and discussion with the specific patient.

It is important to note that the involvement of doctors of optometry and post-cataract care is not a new phenomenon. Optometrists have been providing such care in conjunction with the operating surgeons for many years.

Data is available from the Food and Drug Administration on complications and adverse reactions for post-cataract intraocular lens patients. The diagnosis of every one of these potential problems is within the scope of the practice of doctors of optometry.

Senator, I would add that according to professional liability underwriters there has been no appreciable increase in premiums for doctors of optometry since post-operative coverage began in 1981.

It is important to reemphasize that I believe the decision to involve the doctor of optometry in post-operative care rests with the surgeon, based on an evaluation of the specific case, the surgeon's best medical judgment and the desires of the patient.

That is really what the issue is all about—doctors making decisions they believe in and feel comfortable with, taking into consideration many factors, the main factor being what is best for the patient.

This referral process is not unique to the area of eye and vision care, but is really no different than other situations in the health care system such as the relationship between cardiologists and cardiovascular surgeons or family practitioners and surgeons.

As I stated a few moments ago a growing number of ophthalmic surgeons have become comfortable with comanaging post-cataract patients. Others within ophthalmology do not share this philosophy.

This difference of opinion within the ophthalmological community itself is an element we believe the committee should focus on to fully understand the issue. There is ample evidence to suggest that the American Academy of Ophthalmology and its officers are engaged in a systematic effort to exclude doctors of optometry from providing any post-operative services. These activities are in direct conflict with the Federal Trade Commission's 1983 advisory opinion conditionally approving the AAO code of ethics.

In its letter of approval the FTC stated that the code as approved, quote, would not prevent ophthalmologists from arranging for optometrists to provide post-operative care services consistent with State law.

We have recently submitted a request to the Federal Trade Commission to conduct an investigation of actions by the AAO with regard to its code of ethics, a copy of which has been provided to your staff.

The bottom line in discussing this issue should be patient care. No doctor should act in a way he considers to be against his best judgment and in the patient's welfare. It has been suggested that the global fee and modifier approach to paying for cataract surgery and post-operative care may be causing this to occur.

I think that may be an oversimplification. We stand ready to seek sensible solutions that assure access to quality care for patients and the right of practitioners to render care within their scope of practice.

Thank you.

[The prepared statement of Dr. Hanlen follows:]

American Optometric Association
1505 Prince Street ● Alexandria, VA 22314 ● (703) 739-9200

TESTIMONY OF THE

AMERICAN OPTOMETRIC ASSOCIATION

Presented May 23, 1988

By Harvey P. Hanlen, O.D.

to the

Special Committee on Aging

United States Senate

Mr. Chairman, I am Harvey Hanlen, a doctor of optometry in private practice in State College, Pennsylvania and Chairman of the American Optometric Association Federal Relations Committee. AOA is the national organization representing over 26,000 doctors of optometry and students.

I appreciate the opportunity to appear before you today to discuss the issue of reimbursement for cataract surgery and post-operative care under Medicare. You have expressed concern over reports of kickbacks, induced referrals and undue restrictions on medical decisionmaking related to this procedure. Let me state at the outset, these are serious concerns, ones not taken lightly by our association. We have always supported efforts to address clear cases of fraud and abuse in Medicare and will continue to do so. For that reason, we have been pleased to cooperate with both the Office of Inspector General and the General Accounting Office in their investigations into this issue.

It is our understanding that neither of these studies are yet complete and we do not wish to speculate on their potential findings at this time. However, I am pleased to address the issue of referrals for consultation and comanagement between doctors of optometry and ophthalmologists and specifically some of the questions raised by the anecdotal reports which led to these investigations and which have also been provided to your Committee.

First, I want to emphasize that there is a very legitimate and natural referral relationship between doctors of optometry and ophthalmologists in rendering care for cataract patients. Doctors of optometry are clinically trained and legally licensed in all 50 states to diagnose cataracts as well as other ocular diseases and systemic diseases with ocular manifestations. In fact, because of their role as primary care providers, it has been estimated by HCFA that doctors of optometry diagnose nearly 70 percent of developing cataracts in this country.

Once the diagnosis is made, the doctor of optometry must determine the rate of development of the cataract, the degree to which it is affecting the patient's vision as well as visual health, explain the options to the patient and plan for the referring of the patient to an ophthalmic surgeon when surgery appears to be indicated.

The decision on where to refer a patient should be based on providing the best potential outcome for that patient; that is, restoration of vision to the optimum level possible with the least potential for complications. Thus, knowledge of the comparative skills and track records of surgeons can and does play an important role.

Let me state firmly that AOA believes referrals that are not based on this "patient welfare" criteria, but instead are motivated solely on some "quid pro quo" economic agreement have no place in the system. We do not condone referrals based on payments from one provider to another, inducements that offer blanket promises, or arrangements that allow providers to bill for services not actually rendered. We believe that evidence of this type of activity should be referred to the Inspector General and we stand ready to cooperate in any way.

I would like to turn now to the specific issue of post-operative care for patients who have received cataract surgery. There are two points I would like to emphasize. First, doctors of optometry are clinically trained and legally licensed to care for post-cataract patients and diagnose complications that can result from this procedure. Second, the decision to involve a doctor of optometry in post-operative care and to what degree rests with the surgeon, based on the professional relationship between the two providers, and following a post-surgical evaluation and discussion with the specific patient by the surgeon.

It is important to note that the involvement of doctors of optometry in post-cataract care is not a new phenomenon. Optometrists have been providing such care in conjunction with the operating surgeon for many years. In 1976, the then Department of Health, Education and Welfare studied this issue at the request of Congress, and concluded that Medicare should pay for post-operative care by doctors of optometry. Congress subsequently amended the Medicare law to allow payment to doctors of optometry in 1980, and such payments have been lawful since July of 1981. The final HEW report, which was based partly on the input of a panel of experts, including three ophthalmologists, stated "The services provided appear to be effective in patient management, including the management of aphakic and cataract patients. They are reasonable, non-experimental, safe and generally acceptable to the vision/eye care community and the public." The report further concluded, with regard to optometric education:

> "Optometry students in their clinical training rotate through affiliated clinics in hospitals, nursing homes, and other community health facilities. Here they examine patients with cataract and aphakia, and detect and diagnose ocular diseases related to these conditions as well as other ocular abnormalities.
>
> On the basis of this educational experience the optometric student must demonstrate a mastery of the skills and knowledge necessary for the diagnosis and management of the cataract and aphakia patient for both graduation and licensure.
>
> The training is designed to provide the capability to diagnose complications of cataract surgery such as shallow anterior chamber, secondary glaucoma, cystoid maculopathy, intraocular infection, Elschnig Pearls, etc.; and the appropriate use of techniques such as biomicroscopy, gonioscopy, tonometry, direct and indirect ophthalmoscopy perimetry, etc., as well as the skilled use of standard optometric techniques applicable to patients with cataract or aphakia."

This point is underscored by looking at data from the Food and Drug Administration on complications and adverse reactions for post-cataract intraocular lens patients. In that data, FDA has broken down all the various types of complications and adverse reactions found in studies of these patients. The diagnosis of every one of these potential problems is within the scope of practice of doctors of optometry. Incidentally, according to FDA statistics the estimated overall rate of complication from cataract surgery is between 3 and 5 percent.

Mr. Chairman, I would add that according to the AOA endorsed carrier for professional liability insurance, there has been no appreciable increase in premiums for doctors of optometry since post-operative coverage began in 1981, nor to our knowledge have there been any malpractice claims or judgements against any doctor of optometry for cases relating to post-operative care.

It is important to emphasize that the decision to involve the doctor of optometry in post-operative care rests with the surgeon, based on an evaluation of the specific case, the surgeon's best medical judgement, and the desires of the patient. That is really what this issue is all about -- doctors making decisions they believe in and feel comfortable with, taking into consideration the specific factors involved.

Mr. Chairman, this entire referral process is not unique to the area of eye/vision care, but is really no different than other situations in the health care system such as the relationship between cardiologists and cardiovascular surgeons or family practitioners and various specialty providers.

A growing number of ophthalmic surgeons, who have observed first hand optometric education and have great confidence in the abilities of doctors of optometry to provide the care needed for post-operative patients, have become comfortable with comanaging post-cataract patients. Others within ophthalmology do not share this philosophy.

This difference of opinion within the ophthalmolgical community itself is an element we believe the Committee should focus on to fully understand this issue. There is ample evidence to suggest that the American Academy of Ophthalmology and its officers are engaged in a systematic effort to exclude doctors of optometry from providing to patients post-operative services which doctors of optometry are permitted by state law to perform. These activities are in direct conflict with the Federal Trade Commission's 1983 Advisory Opinion conditionally approving the AAO Code of Ethics.

This conditional FTC approval of the Academy code hinged partly on commission interpretation of Rule 8 of the code, "Post-Operative Care." Rule 8 states in part that the operating ophthalmologist should provide "those aspects of post-operative care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries)." In its letter of approval, the FTC stated that this rule "would not prevent ophthalmologists from arranging for optometrists to provide post-operative care services consistent with state law."

Mr. Chairman, we would like to reiterate in this regard our firm belief that care rendered by doctors of optometry to post-operative patients is clearly within the scope of optometric practice in the various states. In states where the qualifications and authorization of doctors of optometry to provide such care under state law have been challenged this belief has been upheld. In fact, the North Carolina Board of Medical Examiners requested a ruling in 1986 from the state's Attorney General on this question. The Attorney General concluded "The procedures identified herein as components of post-operative care of cataract surgery patients fall within the definition of optometry when done by a licensed optometrist, and do not constitute the unauthorized practice of medicine." We know of no instance where state law precludes this care.

Since approval of the Code, AAO and some of its officials have conveniently ignored the qualifying and limiting language contained in the code, language which in fact was included at the insistence of the FTC, and have undertaken an effort to discourage and intimidate ophthalmologists from comanaging post-cataract patients with doctors of optometry.

Through a series of public pronouncements and private communications, AAO and its officials have sought to twist the intent of this rule to scare its members into avoiding any comanagement situations. Perhaps the most blatant example of this activity is a most restrictive policy statement on post-operative care published by the Academy in 1987.

This statement starts by delivering the message that most ophthalmologists believe that only ophthalmologists should provide post-operative care and others believe that an ophthalmologist should not operate unless he will provide such care. The statement then pays lip service to the FTC approved code, stating that legal constraints limit "the extent to which" AAO policy may reflect these views. Yet AAO concludes by stating that the ophthalmologist is "uniquely competent and qualified to perform cataract surgery with its presurgical evaluation and post-operative management."

This statement, and other highly publicized activities by the AAO, has sent a chilling signal to AAO members. The signal is that only ophthalmologists should provide post-operative care and that AAO members should boycott optometrists to achieve this exclusionary goal.

While many of these activities appear to be cloaked in a concern about quality, it is clear from remarks by AAO officals that economics is an important motivation. Dr. Hunter Stokes, AAO Secretary for Governmental Relations, declared in a December 15, 1987 interview in Ocular Surgery News: "It would be different if there was a shortage of ophthalmologists and we were so busy we didn't have time to provide post-op care, but that's the farthest thing from the truth." Earlier, in an article in Argus, the official AAO publication, Dr. Stokes also expressed his worry about the economic impact of optometric post-operative care. Noting a "surplus of ophthalmologists in so many parts of the country," Dr. Stokes complained that the "other myopic aspect of optometric post-operative care is the effect it has on other ophthalmologists in the area."

We have recently submitted a request to the Federal Trade Commission to conduct an investigation of these actions by the AAO with regard to its Code of Ethics, and I would be pleased to provide you with a copy of that document.

Mr. Chairman, we do not raise this question to minimize or sweep aside the concerns you have raised. However, we believe strongly that it is an important factor that cannot and should not be ignored.

The bottom line in discussing this issue should be patient care, Mr. Chairman. No doctor should act in a way he considers to be against his best judgement and the patient's welfare. It has been suggested that the global fee and modifier approach to paying for cataract surgery and post-operative care may be causing this to occur. I think that may be an oversimplification, but certainly we are most willing to explore with you and others alternative means of reimbursement that recognize patient care is paramount. We stand ready to work with you to address potential problems and seek sensible solutions that assure access to quality care and the right of practitioners to render care within their scope of practice.

I would be happy to respond to questions.

STATEMENT OF CHARLES BOOTH, DIRECTOR, OFFICE OF REIMBURSEMENT POLICY, HEALTH CARE FINANCING ADMINISTRATION, WASHINGTON, DC

Mr. BOOTH. Senator Heinz, I am Charles Booth, Director of the Office of Reimbursement Policy of the Health Care Financing Administration.

I'm pleased to be here this morning to discuss Medicare payments to ophthalmologists and optometrists for services rendered to cataract surgery.

The Omnibus Reconciliation Act of 1980 permitted optometrists to be paid for services relating to the treatment of patients who had their optic lens removed during cataract surgery. These services include the fitting of corrective eyeglasses, physical examination of the eye, and evaluation of the eye's visual function.

That act also required the Department to submit a report to the Congress on expanding payment to optometrists for other public services which they are licensed to perform under State law.

In that report the Department opposed expanding payments to optometrists because we had no evidence that beneficiaries lacked access to vision care services, and because we were concerned that optometrists might provide duplicative and perhaps unnecessary services.

However, in its 1986 Reconciliation Act, Congress expanded Medicare payment to optometrists to include all Medicare-covered vision care services which they are legally authorized to perform in the State in which they practice.

Concerns have been expressed that direct payment to optometrists under Medicare has introduced financial incentives into the medical decisionmaking process, thereby encouraging optometrists to refer patients for surgery which is either premature or unnecessary.

The claim is made that these incentives have changed referral patterns so that optometrists refer patients for cataract surgery only to surgeons who agree to refer these patients back to them for post-operative care. Finally, questions have been raised concerning the qualifications of optometrists to provide this care, which may be encouraged by the payment provision.

We too are concerned that services provided the Medicare beneficiaries are medically necessary and meet professionally recognized standards of quality. However, it is important to emphasize that we have seen no evidence that the quality of cataract surgery and post-surgical care has declined.

Peer review organizations, PRO's, currently monitor any quality problems that may arise during an inpatient stay for cataract surgery and soon will be reviewing surgical services provided by ambulatory surgery centers and hospital outpatient areas, under the contract cycle beginning October 1, 1988. PRO's in two States, Pennsylvania and Massachusetts, are now beginning this review.

PRO's will not, however, be able to identify most cases with post-operative complications which generally are treated in physicians' offices. PRO's currently do not review care provided in this setting, although they will begin reviewing such care on a pilot basis in January 1989.

When problems are identified in any practice setting, the PRO will take appropriate corrective action, such as practitioner education or, as a last resort, sanctions where warranted.

I would like to turn now to the issue of whether direct payment to optometrists contributes to premature or unnecessary cataract surgery and poor quality post-operative care.

The statutory language which authorizes direct payment of optometrists clearly states that they are to be considered as physicians for all the Medicare-covered vision care services they are licensed to perform under State law.

In the absence of State licensure laws which prohibit optometrists from rendering pre- and post-surgical care, the statute gives us no authority to deny payment to optometrists for this care.

In designing a payment system to implement this provision, we had to guard against duplicative payment. The system used to pay optometrists is based on long-standing payment procedures regarding co-management of surgical patients. This type of co-management is far from unusual.

For example, beneficiaries living in rural areas frequently are referred to regional medical centers for surgery, return home after surgery, and receive follow-up care from physicians in their area. It would be unreasonable to require these beneficiaries to receive post-operative care from their operating surgeon.

For this reason, our payment system identifies instances in which a physician other than the operating surgeon provides pre- or post-operative care to assure that duplicate payments are not made.

With regard to the impact of this payment provision on referral patterns, we see nothing inherently wrong with the establishment of referral patterns between optometrists and ophthalmologists, so long as the patients require cataract surgery.

To the extent that we identify referral patterns which involve fraud or kickbacks, we will, of course, notify the Inspector General's office for investigation and further action.

In conclusion, the Department has implemented the law which requires direct payment of optometrists for Medicare-covered services. In doing so we have instituted safeguards to protect against duplicative payment for these services.

We believe that quality has not declined in the treatment of beneficiaries undergoing cataract surgery. However, to the extent that PRO's identify poor quality care now and in the future, with their increased review responsibilities, we will take action to correct those problems.

Any further action requiring change of coverage of, or payment for, vision care services, would require a statutory amendment.

Thank you.

[The prepared statement of Mr. Booth follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Washington, D.C. 20201

STATEMENT OF

CHARLES R. BOOTH

DIRECTOR

OFFICE OF REIMBURSEMENT POLICY

HEALTH CARE FINANCING ADMINISTRATION

BEFORE THE

SENATE SPECIAL COMMITTEE ON AGING

PHILADELPHIA, PENNSYLVANIA

MAY 23, 1988

Senator Heinz, I am Charles Booth, Director of the Office of Reimbursement Policy of the Health Care Financing Administration (HCFA). I am pleased to be here this morning to discuss Medicare payment to ophthalmologists and optometrists for services related to cataract surgery.

BACKGROUND

To provide some background, let me point out that vision care services covered under the Medicare program are limited to those necessary to treat eye diseases such as glaucoma or cataracts. Prior to July 1981, optometrists could not be paid directly for any of these services. However, the Omnibus Reconciliation Act of 1980 permitted optometrists to be paid for services related to the treatment of patients who have had their optic lenses removed during cataract surgery. These services include fitting of corrective eyeglasses, physical examination of the eye, and evaluation of the eye's visual function.

That Act also required the Department to submit a report to Congress on expanding payment to optometrists for other covered services which they are licensed to perform under State law. In that report, the Department opposed expanding payment to optometrists because we had no evidence that beneficiaries lacked access to vision care services and because we were concerned that optometrists might provide duplicative and perhaps unnecessary services.

However, in its 1986 reconciliation act, Congress expanded Medicare payment to optometrists to include all Medicare-covered vision care services which they are legally authorized to perform in the State in which they practice.

In April 1987, HCFA issued instructions to the carriers notifying them of this coverage change and providing guidance regarding payment for optometrists' services. Based on long-standing policy regarding medical services not provided by the operating surgeon, we instructed our carriers to develop the means to identify pre- or post-surgical services provided by an optometrist and to avoid paying both the surgeon and the optometrist for the same services.

ISSUES

Concerns have been expressed that direct payment of optometrists under Medicare has introduced financial incentives into the medical decision-making process, thereby encouraging optometrists to refer patients for surgery which is either premature or unnecessary. The claim is made that these incentives have changed referral patterns so that optometrists refer patients for cataract surgery only to surgeons who agree to refer these patients back to them for post-operative care. Finally, questions have been raised concerning the qualifications of optometrists to provide this care, which may be encouraged by the payment provision.

HCFA'S ROLE IN ADDRESSING THESE ISSUES

We too are concerned that services provided to Medicare beneficiaries are medically necessary and meet professionally recognized standards of quality. However, it is important to emphasize that we have seen no evidence that the quality of cataract surgery and post-surgical care has declined. There will always be anecdotal instances of poor quality in any area of medical practice, but Ira Abramson, M.D., in Cataract Surgery, reports that the success rate of cataract surgery with intraocular lens insertions is 99 percent.

Peer review organizations (PRO) currently monitor any quality problems that may arise during an inpatient stay for cataract surgery and soon will be reviewing surgical services provided in Ambulatory Surgery Centers and hospital outpatient areas, under the contract cycle beginning October 1, 1988. PROs in two states, Pennsylvania and Massachusetts, are now beginning this review.

PROs will not, however, be able to identify most cases with post-operative complications, which generally are treated in physicians' offices. PROs currently do not review care provided in this setting, although they will begin reviewing such care on a pilot basis in January 1989.

When problems are identified in any practice setting, the PRO will take appropriate corrective action such as practitioner education or, as a last resort, sanctions where warranted.

Payment Policy. I would like to turn now to the issue of whether direct payment to optometrists contributes to premature or unnecessary cataract surgery and poor quality post-operative care.

The statutory langauge which authorizes direct payment of optometrists clearly states that they are to be considered as "physicians" for all the Medicare-covered vision care services they are licensed to perform under State law. In the absence of State licensure laws which prohibit optometrists from rendering pre- and post-surgical care, the statute gives us no authority to deny payment to optometrists for this care.

In designing a payment system to implement this provision, we had to guard against duplicative payment. The system used to pay optometrists is based on long-standing payment procedures regarding co-management of surgical patients. This type of co-management is far from unusual. For example, beneficiaries living in rural areas frequently are referred to regional medical centers for surgery, return home after the surgery, and receive follow-up care from physicians in their area. It would be unreasonable to require these beneficiaries to receive post-operative care from their operating surgeon. For this reason, our payment system identifies instances in which a physician other than the operating surgeon provides pre- or post-operative care to assure that duplicate payments are not made.

With regard to the impact of this payment provision on referral patterns, we see nothing inherently wrong with the establishment of referral patterns between optometrists and ophthalmologists, so long as the patients require cataract surgery. To the extent that we identify referral patterns which involve fraud or kickbacks, we will of course notify the Inspector General's office for investigation and further action.

IV. CONCLUSION

In conclusion, the Department has implemented the law which requires direct payment of optometrists for Medicare-covered services. In so doing, we have instituted safeguards to protect against duplicative payment for these services.

We believe that quality has not declined in the treatment of beneficiaries undergoing cataract surgery. However, to the extent that PROs identify poor quality care now and in the future, with their increased review responsibilities, we will take action to correct these problems.

Any further actions regarding changes in coverage of or payment for vision care services would require a statutory amendment.

I will be happy to answer any questions you may have.

Senator HEINZ. Thank you very much, Mr. Booth.
Mr. Kriss.

STATEMENT OF ERIC KRISS, PRESIDENT AND CHAIRMAN, MEDIVISION, BOSTON, MA

Mr. KRISS. Senator Heinz, I am Eric Kriss, Chairman and President of MediVision, the Nation's largest eye care provider serving patients in 17 States.

Our goal is to eliminate all poor quality care in America and I'd like to thank you for holding this hearing so that we can all improve upon what we do.

There are five questions that I would like to address today.

First, can optometrists be integrated into surgical eye care delivery with high quality results?

Second, should optometrists be integrated with surgical care?

Third, are eye care delivery systems that support the integration of optometry and ophthalmology gaining market share, and if so, why?

Fourth what is the competitive response to these new delivery systems?

And finally, what steps can be taken to eliminate the potential for fraud and abuse?

The answer to the first question—can optometrists be integrated into surgical eye care delivery with high quality results—is an emphatic yes. The MediVision network itself is proof.

We have treated hundreds of thousands of patients and have integrated over 2,000 optometrists into our system. From the founding of our organization in 1984 through the end of the current calendar year, MediVision physicians will have performed roughly 100,000 cataract/implant procedures.

Of this voluminous universe of surgical patients, we know of not a single malpractice claim or judgment that has resulted from the delegation of post-operative care to optometrists. We attribute this unprecedented record to the high quality of care provided both within each MediVision center and by local optometrists serving as each patient's primary eye care doctor. Our integrated system clearly works to provide care of unsurpassed quality.

The next question is: Should optometrists be integrated into surgical care?

Again, the answer is yes. Optometrists already diagnose 20 to 40 percent of all eye diseases and are recognized as primary eye care doctors in most rural areas of America. Removing optometrists would restrict the delivery of eye care to many older and poorer citizens.

Post-operative case management by optometrists has been proven medically effective, and is an appropriate division of labor among eye care practitioners.

Are eye care delivery systems that support the integration of optometry and ophthalmology gaining market share, and if so, why?

Indeed, these systems are gaining market share. The high quality combination of surgical specialization and continuing personal attention from optometrists generates a powerful degree of patient goodwill.

This goodwill has fostered MediVision's growth from 0 to 3 percent of the market share nationally since 1984 as an example. Of course, a corollary to this increased market share is that some practitioners have been losing patients due to the heightened intensity of the competition, and these practitioners are obviously upset.

It is no surprise that in markets such as the Carolinas, Tennessee, and Georgia, where eye care centers with an integrated focus have become very successful and have received widespread public acceptance, that there has been a significant amount of anticompetitive activity on the part of some underemployed ophthalmologists.

Specifically then, what has been the competitive response? Faced with this new breed of care delivery, many ophthalmologists have banded together through existing organizations to attempt to thwart the very concept of integration, mostly through unsubstantiated claims of poor quality care. But let's not be misled.

Economic self-interest is behind all of this talk. In order to protect its flanks from eroding market share, traditional ophthalmology, represented both by the American Academy and by State associations, has become engaged in political string pulling, anticompetitive actions, and lawsuits.

In short, ophthalmologists are acting like a cartel. We know what cartels do from our experience with OPEC: they try to keep prices up, keep the level of services down, and threaten to undermine the free market forces that are at work here.

I urge Senator Heinz and the Congress not to take hasty action which will strengthen this cartel.

However, there are an unscrupulous few who try fraudulent means to subvert legitimate competition, and I think that should be the focus of our inquiry.

So finally: What steps can be taken to eliminate the potential for fraud and abuse?

One major positive step has already been taken by Congress in allowing optometrists to bill the program directly for services provided to Medicare beneficiaries. Direct Medicare payment to optometrists has eliminated an opportunity for financial inducement. Today, rather than financial ties to surgeons, optometrists receive direct payment from the Medicare Program.

The system may be improved by eliminating non-cash abusive incentives and unfair marketing practices. We have a few specific suggestions:

Eliminate free travel and vacation junkets offered by some ophthalmologists to referring optometrists.

Stop abusive marketing practices by intraocular lens manufacturers who offer to generate referrals. The cost of these programs is in effect added to the intraocular lens invoice which is then paid by Medicare.

Curtail excessive gift giving, below-market rentals, and so forth. I thank you very much for your consideration.

[The prepared statement of Mr. Kriss follows:]

TESTIMONY OF ERIC A. KRISS
CHAIRMAN AND PRESIDENT
MEDIVISION, INC.

BEFORE THE

SPECIAL COMMITTEE ON AGING
THE UNITED STATES SENATE

MAY 23, 1988

I'd first like to thank Senator Heinz for giving us the opportunity to be here this morning to provide testimony regarding the current Medicare reimbursement system as it pertains to eye care, and particularly with regard to the nature of relationships between practitioners in the delivery of that care.

We've boiled the focus of this hearing down to five salient questions. These questions are:

Can optometrists be integrated into surgical eye care delivery with high quality results?

Should optometrists be integrated into surgical care?

Are eye care delivery systems that support the integration of optometry and ophthalmology gaining market share? If so, why?

What is the competitive response to these new systems?

What steps can be taken to eliminate the potential for fraud and abuse?

Each of these questions will be addressed in turn.

1) Can optometrists be integrated into surgical eye care delivery with high quality results?

The answer to this question is an emphatic "yes." The MediVision network is proof. We've treated thousands and thousands of patients, and have integrated over 2,000 optometrists into our system. From the founding of our organization in 1984 through the end of the current calendar year, MediVision physicians will have performed roughly 100,000 cataract/implant procedures. Of this voluminous universe of surgical patients, we know of not a single malpractice claim or judgment that has resulted from the delegation of post-operative care to optometrists. We attribute this unprecedented record to the high quality of care provided both within each MediVision center and by local optometrists serving as each patient's primary care eye doctor. Our integrated system clearly works to provide care of unsurpassed quality.

2) Should optometrists be integrated into surgical care?

Again, the answer is yes. Optometrists already diagnose 20% to 40% of all eye disease and are recognized as primary eye care doctors in most rural areas of America. Removing optometrists would restrict the delivery of eye care to many older and poorer citizens.

Post-operative case management by optometrists has been proven medically effective, and is an appropriate division of labor among eye care practitioners. The best use of a surgical sub-specialist's time is in the provision of surgical services by examining patient candidates for surgery, performing needed surgical procedures, and examining surgical patients both 24 hours after surgery, periodically through the post-operative case management period, and sporadically on an as needed basis in consultation with the primary care optometrist.

By contrast, the primary care optometrist's time is best used in providing refractions, fitting patients for eyeglasses and contact lenses, diagnosing and treating simple eye disorders and monitoring the progress of surgical patients through the post-operative healing process.

3) Are eye care delivery systems that support the integration of optometry and ophthalmology gaining market share? If so, why?

Indeed they are. The high quality combination of surgical specialization and continuing personal attention from optometrists generates a powerful degree of patient goodwill. This goodwill has fostered MediVision's growth from zero to 3% market share nationally since 1984. Of course, a corollary to this increased market share is that some practitioners have been losing a lot of business due to the heightened intensity of competition. These practitioners are obviously upset. It is no surprise that in markets such as the Carolinas, Tennessee and Georgia, where eye care centers with an integrated focus have become very successful and received widespread public acceptance, there has been a significant amount of anti-competitive activity on the part of organized ophthalmology.

4) What is the competitive response?

Faced with this new breed of competition, many ophthalmologists have banded together through existing organizations to attempt to thwart the very concept of integration. In order to protect its flanks from eroding market share, organized ophthalmology, represented both by the American Academy and by state associations, has become engaged in political activism, name-calling, and lawsuits. Here are some examples of these activities:

> a) The American Academy of Ophthalmology has attempted to use the congressionally-mandated pre-certification program as a means to achieve its goal of prohibiting optometric post-operative case management -- an attempt which has been met by the Health Care Financing Administration with a resoundingly negative response;
>
> b) A North Carolina Board of Medical Examiners motion decrying optometric post-operative care as the unauthorized practice of medicine was explicitly overturned by the state attorney general;
>
> c) The Virginia Society of Ophthalmology issued a letter which interpreted an agreement between Virginia's boards of medicine and optometry in such a way as to lead its membership to believe that

the agreement was more restrictive towards optometric post-operative case management than is actually the case.

Several other examples exist of organized ophthalmology's attempts to restrict optometric practice.

One inroad the Academy has made is represented by a new coverage guideline issued by its captive malpractice insurer, Ophthalmic Mutual Insurance Company, which recently restricted its coverage to preclude post-operative care by other than the operating surgeon or another ophthalmologist. Based on our experience, we question the actuarial basis of this coverage guideline. In essence, organized ophthalmology has only been successful in policy areas in which it has sole province. Publicly accountable policy typically supports optometric post-operative case management because it is medically effective and serves the best interest of patients.

Some competitors, faced with integrated care delivery for the first time, recognize the wave of the future and adapt to changing times rather adopting a cartel mentality to fight it. Unfortunately, a few practitioners and companies try fraudulent means to subvert legitimate competition.

5) What steps can be taken to eliminate the potential for fraud and abuse?

One major positive step has already been taken by the Congress in allowing optometrists to bill the program directly for services provided to Medicare beneficiaries. Direct Medicare payment to optometrists has eliminated in most instances the appearance of impropriety on the part of ophthalmologists making payments to subcontracting optometrists for services rendered. Today, rather than financial arrangements between practitioners for the provision of needed services, optometrists receive direct payment from the Medicare program.

The system may be improved by eliminating non-cash abusive incentives and unfair marketing practices. Specifically, we suggest guidelines to:

a) eliminate free travel and vacation junkets offered by ophthalmologists to referring optometrists;

b) stop abusive marketing practices by some intraocular lens manufacturers who offer to generate referrals (the cost of these programs is in effect added to the intraocular lens invoice and paid by Medicare);

c) curtail excessive gift-giving, below-market rentals, and other non-cash inducements.

Thank you very much for your consideration.

Testimony of Eric A. Kriss
Special Committee on Aging
May 23, 1988

ABOUT MEDIVISION

MediVision, Inc., headquartered in Boston, Massachusetts, is a network of 30 eye care centers in 17 states. The MediVision network is in the forefront of a revolution in the delivery of eye care to American citizens. In 1987, MediVision facilities and physicians delivered 3% of the nation's surgical eye care, establishing the network as the market leader in a fragmented industry.

Because of its specialization in eye surgery, the MediVision network serves a disproportionate number of elderly citizens, many of whom are poor and without supplemental insurance. This specialization also allows MediVision to deliver eye care of the highest possible quality while presenting the lowest possible cost to the federal Medicare program.

The cost advantage MediVision facilities represent to the Medicare program may be summarized by assuming that, in the company's absence, most cataract/implant surgeries would be performed in outpatient departments of hospitals at roughly $1500 per case. By contrast, the same surgery provided in a MediVision ambulatory surgical center costs Medicare just $480, a savings of $1000 per case as compared to the hospital environment. During 1987 alone, over 25,000 cataract/implant surgeries were performed through MediVision's eye care centers, providing Medicare program savings of $25 million.

MediVision actively encourages the coordination of care among optometrists and ophthalmologists. In fact, the concept of integrated care is central to the MediVision philosophy. By working closely with a patient's optometrist, who is in effect the primary care eye doctor, a MediVision ophthalmologist is best able to refine and perfect the art of eye microsurgery. By hosting continuing education and training programs for local optometrists, MediVision doctors also provide vital professional training and thereby enhance the overall eye health of a community.

Patients and their families are comfortable with an integrated system for several reasons. For one thing, they know that a surgical sub-specialist is truly expert in delivering surgical eye care. As with any profession, the quality and effectiveness of the delivery of a specific service only increases as an individual becomes familiar with different problems which may arise through the experience afforded by repetition. A cataract surgeon performing 500 surgeries annually will very likely become more expert than one performing 50. Furthermore, when the operating surgeon deems it medically appropriate, the patient returns to the office of his primary care optometrist, who frequently is located much closer to the patient's home.

MediVision's commitment to eye care of the highest quality is demonstrated through its continuing education programs, through which community optometrists earn credit while keeping abreast of current developments in the state-of-the-art delivery of high quality, cost-effective eye care.

At each MediVision center, a doctor of optometry serves as the center director. All center directors conduct six seminars each year at which continuing education credits are available to community optometrists. The high caliber of MediVision's corps of center directors is underscored by the fact that three out of every four of the teachers and lecturers at optometry's 1988 Southern Congress was a center director, as were close to half of the instructors at the annual meeting of the American Optometric Association. Of all 1987 graduates of schools of optometry in the United States, 10% had completed an internship rotation at a MediVision eye care center. Finally, of 55 optometric residency programs nationally, 30 are offered by schools of optometry, 15 by the Veterans' Administration, and 10 by MediVision eye care centers.

Senator **Heinz**. Thank you very much, Mr. Kriss.

Well, gentlemen, you've all testified to the subject of the hearing from a variety of points of view but I want to see if I can't draw out some common threads from your testimony.

But first I want to return to Mr. Mitchell whose work and that of the OIG generally has been extremely valuable to our committee over the years. Indeed, I might say, Mr. Mitchell, without you and Stanley Ross' great help it would not have been possible to frame the Fraud and Abuse Act we were able to pass after some 4 years of effort trying to pass in the Senate and the House 1987 legislation you referred to and gave me such generous credit for writing.

Let me ask you this: Most of us have heard about your, the FBI's, and the Attorney General's investigation of kickbacks involving claims of physicians for referrals to clinical labs serving Pennsylvania and New Jersey. You referred to that in your statement.

Are we facing a similar situation with some of the cases of payments for cataract patient referrals that we've heard about today? Take, for example, a hypothetical case where an ophthalmologist agrees to pay an optometrist a flat rate for each referral independent of any amount of post-operative involvement, is that a kickback and would it be illegal?

Mr. **Mitchell**. Well, it's difficult for me to answer for the judicial system, Senator, on whether or not it is a kickback, but I would say it is an item that the Office of the Inspector General would take under investigation.

Senator **Heinz**. Now, you found only 3 percent of ophthalmologists using modifier 54, suggesting that optometrists are doing very little post-operative care, but at the same time you found that 28 percent of ophthalmologists in their interviews said they used optometrists for post-operative care. That's quite a difference.

How do you explain that difference between 3 and 28 percent?

Mr. **Mitchell**. We've not finished our analysis, Senator, but the indications are that you were looking at a data base that's a little old and that the phenomenon is growing and if you look at it from a year from now, the 3 percent will be much greater.

Senator **Heinz**. If that's so, is it because you believe your data simply are lagging behind practice?

Mr. **Mitchell**. We believe the ophthalmologists are lagging behind in their use of the modifier 54.

Senator **Heinz**. Now, in your testimony I believe you found that there were some strong associated relationships, namely that those surgeons that used optometrists were highly correlated with referrals from optometrists, short post-operative involvement of surgeons with their patients, higher incomes to the tune of $1.9 million compared to $930,000 a year in payments for Medicare.

Does that pattern show that there is a very strong financial incentive for ophthalmologists to use optometrists and perhaps as a result skimp on necessary post-operative care?

Mr. **Mitchell**. Certainly it appears, Senator, that there's a strong financial incentive to enter into these arrangements. Whether or not that would lead to the skimping on the post-surgical care, our data does not yet reveal, although it is indicated that the ophthalmologist who entered into these arrangements, have a much shorter post-operative contact with the patient than those who do not.

Senator HEINZ. I assume that you are not qualified to comment on whether a shorter post-operative involvement on the part of the ophthalmologist does or does not constitute a skimping on care?

Mr. MITCHELL. That's correct, Senator, I'm not.

Senator HEINZ. Now, you also found that 22 percent of ophthalmologists do not examine their patients immediately before and the day after surgery.

Now, I understand you're not a physician but based on what you've heard today, and what we've learned generally about the importance of the surgeon's role here, doesn't that strike you as potentially a very serious quality issue?

Mr. MITCHELL. It would seem that it's something that we need to followup on, Senator, and keep a close eye on.

A very interesting thing to us was that 88 percent of the ophthalmologists who did use the modifier 54 also saw the patient post-op.

Senator HEINZ. So what you're saying is the fact that someone is using modifier 54 doesn't necessarily mean that they are skimping on post-operative care?

Mr. MITCHELL. That's the indication to us.

Senator HEINZ. Is there a need for a stronger peer review organization role in quality oversight, prior certification of surgical necessity? Is there a need for mandatory second opinion?

Mr. MITCHELL. We believe the answer to both is yes.

Senator HEINZ. I realize that you cannot discuss the specifics of any of the cataract cases that your office is investigating but I understand you are investigating some. Is that correct?

Mr. MITCHELL. That's correct, sir.

Senator HEINZ. Can you, without revealing anything you shouldn't reveal, at least give us some ideas of the type, generally speaking, of cases that you are investigating?

Do they all involve referral networks, for example, or are these types of arrangements just one of several kinds of questionable practices you're looking into?

Mr. MITCHELL. Of the active cases that we have open, Senator, 60 some odd, well over 10 percent of them are cases that involve referral processes of one type or another between ophthalmologists and optometrists, and this referral arrangement is the fastest growing area of complaints, if you will, that we are receiving in the area.

Senator HEINZ. Thank you very much, Mr. Mitchell.

I'm going to ask Doctor Stokes, Doctor Hanlen and Mr. Kriss to consider themselves a mini-panel for the purpose of answering a series of questions, to see if we can't get some consensus on how we take action to address those problems.

So I'm going to ask a question and then I'm going to go right down to Doctor Stokes, Doctor Hanlen, and Mr. Kriss.

I'm sorry, Mr. Booth, that we're going to skip over you for the moment, but don't worry, we don't intend to ignore you. We appreciate your being here.

Mr. BOOTH. Thank you.

Senator HEINZ. Now, first, do you all agree that to the extent that kickbacks or induced referrals exist, that they are unethical, that they do put patients at an unnecessary risk, independent of practice, style or volume, and should be stopped?

Doctor Stokes, do you agree?

Dr. **Stokes**. Yes, I do, and I think the Medicare fraud and abuse law is necessary.

Dr. **Hanlen**. I do agree to that.

Senator **Heinz**. Mr. Kriss.

Mr. **Kriss**. Absolutely agree.

Senator **Heinz**. I'm glad you all agreed. I'd hate to be saying no to that question. None of you are beating your wives currently, I'm very pleased.

Dr. **Stokes**. Is that the question?

Senator **Heinz**. Am I correct in saying that you find problems with the current reimbursement approach of the modifier either because its application to cataract surgery is inappropriate or because it is being misused?

Dr. Stokes.

Dr. **Stokes**. That's correct.

Senator **Heinz**. Doctor Hanlen?

Dr. **Hanlen**. No, I don't believe there's a major problem with the modifier situation at this time.

Senator **Heinz**. Mr. Kriss.

Mr. **Kriss**. I concur with Doctor Hanlen, I don't believe there's a major problem at this time.

Senator **Heinz**. Now, am I correct that the basic standards of good cataract surgical care include the following: First, a thorough pre-op eye health exam by the attending surgeon or consultation with the family or other physician; number two, a decision by the surgeon and the patient that surgery is necessary; number three, at least 1 day after, post-operative exam by the attending surgeon, and fourth, the surgeon's continued management of care until he or she determines that the patient may be or should be discharged to another provider?

Doctor Stokes?

Dr. **Stokes**. I agree that those are among the minimum standards. I would think that post-operative care would need to be amplified beyond what you said.

Senator **Heinz**. Doctor Hanlen?

Dr. **Hanlen**. I agree with the exception that it's possible at the end of that 24-hour visit that the surgeon may confirm that the patient may be seen by a doctor of optometry for the continued post-operative care.

Senator **Heinz**. The fourth point is the surgeon's continued management of care which certainly could extend well beyond the first visit, what I referred to as within the 24 hours after surgery. It may extend well beyond that.

I did not mean to imply that standard medical practice was for the ophthalmologist to have one visit to the patient and adios, that was not the implication, so you correctly diagnosed what I meant.

Mr. Kriss.

Mr. **Kriss**. I would agree with those standards.

Senator **Heinz**. Now, assuming that we can, and indeed we just did, agree on these basic principles of care, do you believe that Medicare could protect against some of the problems we've heard about today by setting similar standards within the framework of our reimbursement and quality review structures independent of practice or styles?

Doctor Stokes.

Dr. **Stokes**. Yes, I think they could and I think they should.

Senator **Heinz**. Doctor Hanlen.

Dr. **Hanlen**. I believe it can be done.

Senator **Keinz**. Mr. Kriss.

Mr. **Kriss**. I believe we do not need additional regulation. There are strong market-forces at work that encourage quality care.

Senator **Heinz**. So we should do absolutely nothing?

Mr. **Kriss**. Yes, in terms of regulating standards for post-operative care.

Senator **Heinz**. Medicare has no standards.

Mr. **Kriss**. I believe we should avoid the urge to legislate more exact standards.

Senator **Heinz**. Just ignore the problem as if there is no problem?

Mr. **Kriss**. There's no quality problem, Senator.

Senator **Heinz**. Specifically, do you, or any of you, believe in a stronger quality review of pre-op; surgical; and post-op care? Let me put the question this way, that PRO review of pre-op surgical and post-operative care is desirable?

Dr. Stokes?

Dr. **Stokes**. I think it's critical and the Academy has been very disappointed that HCFA chose in its original remarks to the State carriers not to insist that post-operative care be defined relative to the standard of care in each State when approving cataract surgery.

I must add that we're pleased now that HCFA is going to insist that each cataract be evaluated by the PRO in the new standards that are coming out.

Senator **Heinz**. That's an unusual step because they're insisting on mandatory evaluation of each decision. Is that correct?

Dr. **Stokes**. Yes. It is unusual and it's going to be time-consuming for the PRO. We feel that under the present circumstances it doesn't go nearly far enough in terms of assuring that only necessary surgery be done.

Senator **Heinz**. Doctor Hanlen, then do you agree on the PRO rule?

Dr. **Hanlen**. Yes. I think it may be desirable, although not in every surgical situation.

Mr. **Kriss**. I think to a large extent PRO review is unnecessary.

Senator **Heinz**. What about whether there should be a second surgical opinion?

Doctor Stokes, it's been strongly recommended by OIG.

Dr. **Stokes**. The general attitude of physicians is that second opinions would create a major breakdown in the orderly providing of services because of the inordinate delays in getting the patient to a second opinion, assembling the information.

I think in all honesty from a very personal standpoint that that is the only way that we would ever get at the absolute appreciation of the problem. Some sort of random second opinion or some sort of a second opinion program in one particular site as an ongoing study.

Senator HEINZ. So possibly as a sample?

Dr. STOKES. Yes, sir.

Senator HEINZ. But not necessarily 100 percent?

Dr. STOKES. 100 percent for second opinions for cataract surgery is a million second opinions a year and that would be an incredible task.

Senator HEINZ. Doctor Hanlen, how do you feel about second opinions?

Dr. HANLEN. I agree that second opinions may be necessary some of the time.

However, I believe that in many situations where an optometrist has referred that patient to an ophthalmologist for surgery there have been two opinions there at that point in time.

Senator HEINZ. Mr. Kriss?

Mr. KRISS. I think all citizens have a right to second, third, fourth, or hundredth opinion, but I don't think the Government should get involved in mandating opinions and creating additional healthcare costs.

Senator HEINZ. To the extent that there's a significant difference in opinion and a lack of research to sort out the gray area between post-op day one or perhaps week one and the final refraction in fitting of glasses, which both O.D. and M.D. do, I understand, do you all see a benefit to doing some outcome research, calling the panel together to review the issue of M.D. and O.D. roles in post-op care?

Doctor Stokes?

Dr. STOKES. Outcome research in terms of the final result from the operation?

Senator HEINZ. Yes, but with a view to establishing from the standpoint of Medicare the boundaries within which Medicare would reimburse the ophthalmologist and where they would sequentially reimburse the O.D.'s, the optometrists.

Dr. STOKES. I think that that would be interesting information to have.

I would point out that in both cases of the tragedies we heard of in the earlier panel, that's a very unusual situation. That's not common, to lose an eye because of optometric post-operative management. There are problems with that, but I would think if you're going to have any study on outcome, the most critical thing would be go back to the beginning and there an absolute mandatory second opinion by another ophthalmologist.

The only second opinion program in Medicare is one which requires that the second opinion be provided by a person who can provide the service. An optometric second opinion for cataract surgery is irrelevant.

So I would think that outcome would be an interesting factor but it would only be one factor we would have to have mandatory second opinion up front.

Senator HEINZ. You testified a moment ago we should unbundle?

Dr. STOKES. No, sir.

Senator HEINZ. You did not. It was the other two ophthalmologists. I apologize.

Dr. STOKES. No, they said to rebundle.

Senator HEINZ. Excuse me, all three of you agree that it was a mistake to unbundle?

Dr. STOKES. Yes, sir.

Senator HEINZ. There are two things that people seem to agree to upon here today. One is that optometrists, O.D.'s, have a legitimate role to play in assisting in the management of a patient. They not only account for a lot of referrals, but also a lot of necessary and proper things that they can and probably should do.

I say "should" because I'm not a doctor and I can't speak with authority. So nobody is saying, "Cut out the optometrist."

At the same time people are saying, "Well, the way that we're now paying by unbundling is a mistake" and the only way, therefore, that occurs to me that we can address both issues is to say, "All right, we're going to rebundle" but what we're really going to have to do is pay opthalmologists a fee and then pay separately, in a way hopefully that will prevent double billings, optometrists for care that they render.

In order to do that intelligently, there will be a gray area of patient management, that will vary depending on style of practice—nonetheless what we will have to do, I suspect, is to define or require HCFA to define where that gray area ends and the black begins so that we will have that done in some rational or scientific way, hence the studies I suggested.

Dr. STOKES. Yes, sir.

Senator HEINZ. Is there any alternative to that methodology?

Dr. STOKES. I think that—perhaps there are, but think that is probably the most appropriate method. I think what you're saying to redefine the parameters of the bundling?

Senator HEINZ. Yes, Doctor Stokes.

Dr. STOKES. What we would say is that the bundle begins at the time that the patient is seen by someone qualified to do the surgery and declares that the surgery should be done and that that parameter for that global fee or period of time ends when the patient has recovered from the operation and is no longer in danger statistically of a major problem and that usually comes after the sutures have been cut, if that's necessary, which is at least 2 months after the operation.

Senator HEINZ. Really what I'm asking of you, Doctor Hanlen, and of you, Doctor Stokes, and of you, Mr. Kriss, is: Is there any reason that that boundary can't be fairly well defined by experts in the field?

Doctor Hanlen.

Dr. HANLEN. I think the boundary may be defined, but it certainly varies depending upon each individual surgical case.

I think the critical part of the reimbursement mechanism is to insure that a provider is reimbursed for services provided under Medicare. It's appropriate for the care rendered.

Senator HEINZ. I think you agree with me and I agree with the second thing that you said.

Mr. Kriss.

Mr. KRISS. Senator, I'm not sure whether I agree or not. One major problem is that technology is moving so rapidly, I am fearful of attempts to write definitions which are obsolete by the time of publication. We have seen changes in technology over a 10-year period which would make things done today totally unthinkable 10 years ago. It would be unfortunate to have regulations etched in stone which retard our medical advances.

Senator HEINZ. Very well.

Saving HCFA for last, Mr. Booth, in your testimony you indicated that you just did what Congress told you, and maybe you did. I'm certain you didn't do anything that Congress didn't tell you to do.

Mr. BOOTH. Thank you.

Senator HEINZ. And not on every occasion can I say that.

Mr. BOOTH. That's why I thank you.

Senator HEINZ. That's not a compliment.

But, in his testimony, Doctor Stokes indicates that you had some degrees of freedom in the way you interpreted the 1986 law that you did not take advantage of. He basically argued, as I understood his testimony on page 2, that you have not properly insisted on limiting reimbursement to optometrists for only those services that are authorized by each State.

He went on to state that in those States, State law explicitly permits post-operative treatments by O.D.'s. If that is correct, and right now that assertion is unrebutted, then it would appear as if HCFA has taken the broadest possible interpretation of what Congress wrote into the law and did not make an effort to ascertain what was and wasn't authorized by State law, and assumed, as I understand your testimony, that if it wasn't explicitly prohibited by State law, it was okay, as opposed to what was explicitly permitted.

What do you say to that?

Mr. BOOTH. Well, I sort of agree and I sort of disagree.

Senator HEINZ. Next question?

Mr. BOOTH. No, I'd like to continue if I might.

I haven't found any State laws that state specifically whether or not an optometrist can perform post-operative cataract examinations. But in looking at various State laws, it appears that the State laws are somewhat broadly drawn.

For example, to take one not quite at random, the Commonwealth of PA's State law says "under practice of optometry, the use of any and all means or methods for the examination, diagnosis and, except for drugs or surgery, treatment of conditions of the human visual system and shall include the examination for adapting and fitting any and all kinds of lenses including cataract lenses. The use of any and all means or methods for examination, diagnosis and treatment."

Now that's a pretty difficult position it seems to me in this Commonwealth for me to say categorically that an optometrist cannot render post-operative cataract care.

Senator HEINZ. So you're saying not only that the Congress gave you a pretty large hunting license but also that the 50 States have rather ambiguous constraints or restraints that are really beyond you without hiring lawyers and going into court in every State that you would like to take that chance.

Mr. BOOTH. Well, let me state it differently.

What we would do would be to deny the care, as I understand Doctor Stokes' testimony, for post-cataract follow-up care rendered by optometrists, in which case the optometrist would take us to court, and I think properly so, based on the reading of this statute by a non-lawyer.

Senator HEINZ. Let me respond to one other comment you made in your testimony which is that you haven't seen any evidence, as yet, of a decline in the quality of care from cataract surgery or in post-surgical care.

I'm reminded a little bit of an argument I got into with a former HCFA administrator now under indictment and perhaps convicted, Mr. Haddow, about whether or not, and we don't wish your indictment, but if you disagree with me——

Mr. BOOTH. Thank you.

Senator HEINZ. But I had an ongoing battle with HCFA and Mr. Haddow and a few others all since for the most part replaced, not of my doing, really, that there were, under the new DRG system, threats to patient health and good outcomes because people were being discharged sicker and quicker without proper attention to post-discharge care settings.

And the argument provided by HCFA at that time was we have no data that there are any problems. And there was a very good reason, there was no data.

At that point the Health Care Financing Administration didn't look beyond, at that point, the 10th day. It may even have been the third day, I forget, but they only looked for a very limited period after an individual was discharged from the hospital.

Now everybody is kind of sick when they get out of the hospital and you don't improve overnight like that. And what the information failed to pick up was a very worrisome pattern of readmissions to the hospital which has since been now caught and evaluated, and because it's caught and evaluated, we certainly have less of them than we did because we now look at a much longer time frame.

Now I think it's 30 days after discharge. So when you say, and I'm quite certain you're correct insofar as your information goes, that you don't have any information, it could well be because first, you're only looking at inpatient cataract surgery. Is not most surgery outpatient?

Mr. BOOTH. Most cataract surgery, I think well over 95 percent, is outpatient.

Senator HEINZ. So you're only looking at 5 percent and second, you're looking at people who are hospitalized and is it probably not easier to find a doctor in the hospital than it is on the street or in your own home?

Mr. BOOTH. Well, it's certainly easier to recognize them in the hospital, let's put it that way.

Senator HEINZ. Well, I don't know about that, they all wear white coats, don't they?

Mr. BOOTH. Most of them do.

Senator HEINZ. In retrospect would you say that we lack information on this subject?

Mr. BOOTH. I think it's clear that to make the kind of judgment that is required we probably need some additional information.

Senator HEINZ. Do you see any problems with the suggestion that I think we came to some agreement about which is that there is a need for rather expeditious studies done to help define, if Congress decides to rebundle, exactly what the boundaries of payments to ophthalmologists and payments to optometrists ought to be?

Mr. **Booth**. I don't think you can argue very successfully against studies.

I suspect, however, that there will be some dispute over the conclusions of the study. I suspect that ophthalmologists will be arguing for the longest possible follow-up period and optometrists will be arguing somewhat shorter periods. And it's not at all clear that the study will satisfy either faction.

Senator **Heinz**. Very well.

Well, it's 11 a.m. and I have about 16 minutes to catch a train or be shot on arrival in Washington, D.C. Unfortunately, for my constituents, I cannot be in two places at one time.

Let me take 60 seconds to summarize where I think this hearing has brought us.

First, there seems to be broad agreement, but we have some division, that the problems are correctable but most specifically everyone seems to agree that referrals for cataract surgery and follow-up that are motivated principally by financial gain instead of medical judgment are downright wrong, ought to be stopped, and that we should take whatever steps are necessary to prevent it.

Second, I suspect that sitting here today, trying to figure out exactly how we should reimburse ophthalmologists or optometrists is probably beyond the capability of either this panel or this Senator, certainly the latter, but we are going to be receiving a study very shortly from the Congress Office of Technology Assessment on that very question, and after that study is released I hope we'll have an opportunity to revisit the issue more comprehensively and formally to establish some ground rules in this area.

Third, I think it is going to be necessary for Congress to revisit the issue of how we pay for cataract surgery, particularly since the States don't seem to be doing much to help us.

It would have been nice if the States had wonderful, nice, clear rules between the various State academies or boards of licensure that would have helped Mr. Booth and HCFA be much clearer in who could do what and to whom but that's not the case.

Fourth, it seems for me, as testified to by Mr. Mitchell, that indeed we have some good laws on the books that can, if fully and effectively enforced, and I know OIG is intent to do that, can clamp down on the worst abuses, the kickbacks and the other illegal activities, the referrals that have been mentioned, and that can help solve some, but by no means all, of the problems.

One of the problems that clearly needs to be addressed is that of unnecessary surgery. We've been through this kind of issue with pacemakers, where cardiologists on the one hand and cardiac-thoracic surgeons on the other, fed off a system, figuratively and literally, that left them rather financially fat and put patients, maybe somewhere between 15 and 30 percent of them, through an unnecessary pacemaker procedure that was good for the pacemaker industry but not very beneficial to the patients.

So finally I think we have one other mission which we think is partly accomplished here today and that is to embark on an aggressive program of consumer education, not only so that they can tell the difference between an ophthalmologist and an optometrist but to understand first and foremost the need to be seen by a properly qualified surgeon before the operation takes place as well as after the operation takes place, to ask upfront before the surgery takes place, not only whether it is urgent and necessary, but whether there is time to get a second opinion, which to this point is voluntary, but most importantly to have a clear understanding with the physician, the surgeon, the ophthalmologist, about who else is going to be involved in the care of that patient.

So that there is a consciousness of what the surgeon's responsibilities are going to be throughout the post-operative period and at what points the physician will choose to involve, as many quite properly do, optometrists in the care of that patient. But that all of that is understood upfront.

And if that was better understood today without a single law being passed by Congress, or a single change being made by HCFA, or a single investigation being made by the Office of the Inspector General, maybe it would be possible for people like Mrs. McGee and Mrs. Sugarmann to have avoided the unpleasant surprises, very tragic to them and their family, what was inflicted upon them, by what I suspect all of us would agree, was probably a preventable situation that could have, with appropriate post-operative attention by a physician, been avoided.

Finally, I hope that in our discussion today no one is left with the impression that there is anything wrong with cataract surgery.

Cataract surgery, particularly with the events of the last decade, has been a tremendous blessing for literally millions of Americans. The complications that arise from cataract surgery arise, based on the information I've seen, infrequently, certainly not more than 5 percent of the time. Most of those complications are diagnosed, caught, and propertly treated.

So under the worst of circumstances, it is only a fraction of that 5 percent of people who would be at risk, but as we have also seen for that fraction of that 5 percent the effect can be absolutely tragic and we do not want, and I'm glad there is broad agreement from our witnesses here today, the extraordinary financial incentives or rewards that are possible by being a provider to Medicare for cataract surgery, to override the ethics of the medical profession to properly treat people and give them the medical care that they are paying for, that they are entitled to and that they certainly by any standard whatsoever fully deserve.

I think you have all helped us make an excellent record here today of the committee. I thank you all, each and every one of you, for being here, and I declare our hearing adjourned.

[Whereupon, the hearing is concluded at 11:05 a.m.]

APPENDIXES

APPENDIX 1.—TRANSCRIPT OF MAY 23, 1988, TODAY SHOW

Item 1

VMS

330 WEST 42ND STREET NEW YORK, NEW YORK [illegible] (212) 736-2010
2301 WEST THIRD STREET LOS ANGELES, CA 9005[illegible] (213) 380-5011
212 WEST SUPERIOR STREET CHICAGO, ILL 60610 (312) 649-1131
577 HOWARD STREET SAN FRANCISCO, CA 94105 (415) 543-3361
715 BOYLSTON STREET BOSTON, MA 02116 (617) 266-2121
1066 NATIONAL PRESS BUILDING, WASHINGTON, DC 20045 (202) 393-7110
356 FRANKLIN AVENUE HARTFORD, CT 06114 (203) 246-1889
1951 FOURTH AVENUE, SAN DIEGO, CA 92101 (619) 544-1860

A [illegible] Affiliate

TRANSCRIPT

DATE May 23, 1988
TIME 7:00-9:00 AM (CT)
NETWORK NBC-TV
PROGRAM The Today Show

Jane Pauley, co-host:

It used to be that a diagnosis of cataracts meant spending the rest of your life in glasses thick as Coke bottle bottoms. But today, lens implant surgery has replaced those glasses. And last year, about a million Americans, most of them elderly, had the thirty-minute procedure. But now some questions are being raised about whether all of those operations were really necessary.

Each week, Dr. Glen Pomerantz performs between five and ten lens-implant surgeries. But that's not the way it was when he first began practicing in Chattanooga.

Dr. Glen Pomerantz: I was asked to do immediate surgery on a patient who would be sent in by an optometrist.

Pauley: Dr. Pomerantz was recruited by a group of optometrists who needed an ophthalmologist, an M.D., to do the lens-implant surgeries.

Pomerantz: They were constantly pushing me to perform more surgeries. They were asking me to use medical devices that they would supply. They were asking me to relinquish the care of my patient to the family optometrist immediately after surgery so that the flow of revenue would be to the optometric practice.

Pauley: Dr. Pomerantz felt that with so many patients, he couldn't keep up the quality of care.

Pomerantz: I felt that I had abandoned my oath, that I had abandoned my style of practice with which I was very comfortable and which I had met with great success before. And I simply didn't do it.

Isabel M. (Eye Patient): Whether he was an ophthalmologist or an optometrist, an M.D., I couldn't tell you because I don't know him.

Pauley: Across the country, seventy-year-old Isabel M. had her implant surgery. A few days after surgery, her right eye was working perfectly, and then things got dimmer and dimmer.

Isabel M.: I went back and I went back. But see, it didn't do any good to go back. There was too many doctors involved.

Pauley: She finally saw the doctor who performed her surgery two months later.

Isabel M.: And then he told me that it would have to come out...(Isabel is in tears)...that I wouldn't get any better until it did come out.

Pauley: She is now blind in her right eye. Dr. Pomerantz and Isabel M. will be testifying later this morning in Philadelphia before the Senate Select Committee on Aging. The ranking Republican on that committee and chairman of the hearings is Senator John Heinz of Pennsylvania, who joins us this morning from our NBC affiliate in Philadelphia, KYW-TV.
Senator Heinz, good morning.

Senator John Heinz (Republican, Pennsylvania): Good morning, Jane.

Pauley: Do the Medicare reimbursement rules invite questionable arrangements, shall we say, between optometrists who are not M.D.'s, and ophthalmologists who are?

Heinz: Well, I think there's no question about it. They clearly do. It is not necessarily that it's wrong to have optometrists involved, but right now, they can be involved at almost any stage, including doing very necessary work that should only be done by the surgeon or ophthalmologist, a trained M.D..

Pauley: In the case of Isabel M., the woman who eventually lost her right eye, the optometrists, who were not M.D.'s as we say, missed the diagnosis of an infection that a trained opthalmologist, an M.D., probably would not have missed. And she didn't need to lose her right eye. Should we reconsider whether optometrists should be doing post-operative care?

Heinz: Well, I don't think Congress, which authorized having optometrists do some of the care, made a mistake, but I do think we have to define very clearly what it is that optometrists should and should not be reimbursed for. It's our responsibility to set standards consistent with the quality of care. So, we have to go back and revisit that.

Pauley: Dr. Pomerantz says that he couldn't take his complaints to state review boards because, well, I guess, to put it in my own words, the practice of these arrangements were so widespread the doctors were sitting on the boards.

Heinz: Well, there clearly are turf fights at the state level between the boards of ophthalmology and the boards of optometry. It's very confusing to just normal citizens. Since the federal government pays for eighty-five percent of all cataract operations, I think the federal government has to step back in and do what the state boards apparently are basically unable to do, and that's set these standards.

Pauley: Well, the hearings will begin today. Senator Heinz, thank you for joining us.

Heinz: Thank you, Jane.

# # #

APPENDIX 2.—WRITTEN TESTIMONY PERTAINING TO HEARING

Item 1

American Optometric Association
1505 Prince Street ● Alexandria, VA 22314 ● (703) 739-9200

June 20, 1988

Honorable John Heinz
Senate Special Committee on Aging
Room 628
Hart Senate Office Building
United States Senate
Washington, D.C. 20510

Dear Senator Heinz:

The American Optometric Association appreciates the opportunity to provide comments for the record on the hearing held May 23 regarding cataract surgery and post-operative care.

Certainly the most compelling statements presented at the hearing were those of Mrs. McGee and Mrs. Sugarman. Both of these patients have suffered tragic losses and we are most sympathetic to their situation. There are, however, certain facts relating to each case that should be clarified in order to assess their relevance to the issue of optometric/ophthalmological referral relationships. Most importantly, neither case involved an outside referral for surgery and referral back for post-operative care. Both cases were handled entirely by private ophthalmological practices where a doctor of optometry was either an employee or associate of the practice, and all post-operative care was rendered in that setting. In addition, Mrs. Sugarman was not a Medicare covered patient, but a private insurance patient. Thus, to infer that these situations, tragic as they are, were the result of referral arrangements spawned by Medicare reimbursement policies is at variance with the facts in each case.

The testimony in each of these cases left the clear impression that the situation was the result of optometric error. In fairness to the doctors involved in these cases it should be noted that there has been no finding of guilt. Should such findings be forthcoming, they should not be used as an indication of optometric competency any more than isolated cases involving other health care disciplines can be used to question the abilities of an entire profession.

A more substantive and reliable statistic on the competency of optometric post-operative care is the MediVision testimony stating that their centers have performed over 100,000 cataract procedures with not a single malpractice claim or judgement as a result of optometric involvement in post-operative patient care.

Headquarters 243 N Lindbergh Blvd ● St Louis, MO 63141 ● (314) 991-4100

While the AOA is not a party to the dispute between Glenn N. Pomerance, M.D. and his former partners, we are familiar with the situation and believe it is important to note that many of the blanket statements in his testimony are under dispute by those directly involved. This is particularly true of allegations that the group demanded immediate same day surgery for all patients and the immediate return of all patients to the referring optometrists. This entire situation is under litigation.

We are interested in Dr. Pomerance's statement that post-operative care should only be rendered by a competent medical practitioner. Surely Dr. Pomerance did not hold these views when he entered into this arrangement, and he offers no examples of poor care as a reason for his apparent change of heart. Indeed, according to optometrists practicing in the area who were contacted by Dr. Pomerance after he left MediVision and established his own private practice, he had no such change of heart but in fact offered them the opportunity to co-manage post-operative patients on the same terms as when he was at the referral clinic.

The testimony of Walter Wright, M.D. raises serious concerns and levels numerous charges against unnamed optometrists and ophthalmologists in the state of North Carolina. Many of these charges, and many of the cases cited in the "casebook" have been raised numerous times in recent years. In an effort to ascertain the facts in these cases, and take disciplinary action where appropriate, the North Carolina Board of Examiners in Optometry has been attempting to obtain substantive documentation from those who are making the charges. Thus far such documentation has not been forthcoming, and based on the testimony and "casebook", the entire matter is now in the hands of attorneys for the Board in a further attempt to discover the facts in these cases. In the case of certain allegations, notably, references to cash payments for post-operative care and the use of VCR's, it is important to note that to the extent these practices did exist, they were given initial approval by the Medicare carrier in consultation with the HCFA regional office. Upon further reflection, the regional office and the carrier determined the practices to be inappropriate, providers in the state were so informed, and to our knowledge no such arrangements have existed for several years.

Finally, while the testimony by the Office of Inspector General and the Health Care Financing Administration indicates no evidence of widespread abuse in the current system, we are troubled by reports of questionable practices and share your concern over these reports. Certainly AOA would be willing to work with you and other interested parties to look at this entire area in a balanced, dispassionate manner with a goal of assuring access to quality of care, patient freedom of choice, and the right of practitioners to provide care within their legal scope of practice.

Sincerely,

Harvey Hanlen

Harvey P. Hanlen, O.D.

Chairman
Federal Relations Committee

HPH/skd

Item 2

AMPRA AMERICAN MEDICAL PEER REVIEW ASSOCIATION
440 FIRST STREET, N.W. • SUITE 510 • WASHINGTON, D.C. 20001 • (202) 628-1853

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•

Executive Vice President
Andrew Webber

May 18, 1988

Senator John Heinz
U.S. Senate
628 Hart Senate Office Bldg.
Washington, D.C. 20510

Dear Senator Heinz:

On behalf of the American Medical Peer Review Association (AMPRA), I want to take this opportunity to communicate our concerns regarding the expansion of PRO review beyond the hospital setting.

We would first like to bring to your attention that the Medicare Second Opinion program, enacted in the OBRA legislation of 1985 and statutorily mandated for implementation by January 1, 1987, has not been established by the Health Care Financing Administration (HCFA). Proposed regulations on the second opinion program have not, on this late date, been issued. While the AMPRA membership is of some divided opinion regarding the effectiveness of second opinion program for different procedures, there is consensus regarding the importance of a second opinion option in reviewing the appropriateness of cateract surgery. Since the clinical indicator for treatment is visual acuity levels of the patient, targetted second opinions that would include reexamination of visual acuity prior to surgical treatment would assure the integrity of the clinical information provided by the attending physician before surgery. Retrospective review of the record after surgery cannot verify the information provided on a preprocedure basis because visual acuity has changed as a result of surgical treatment. The use of second opinion would send a strong message to all ophthalmologists that clinical indicators for surgery must be accurate and will be validated through reexamination of the patient.

Secondly, AMPRA is concerned that HCFA has narrowly interpreted the OBRA 1986 authority to expand PRO review to nursing homes and home health agencies. The proposed scope of work for PROs will only require that a percentage of nursing home and home health services, provided to Medicare beneficiaries between thirty day readmissions to hospitals, be reviewed by the PRO. Experience in your home state of Pennsylvania has already demonstrated that this formula for case selection does not yield a high volume of review. AMPRA believes, and has already communicated to HCFA, that if we are serious about overseeing quality for post acute care services, this element of the PRO review program must be redesigned.

Finally, AMPRA believes that planning must begin immediately for the inevitable advent of PRO review in physician offices. We applaud your efforts in securing agreements from the Administration to begin pilot testing of PRO ambulatory review methodologies and look forward to working with your office and HCFA in the design of these efforts. In addition to the pilot projects, AMPRA would hope that work would begin within HCFA on establishing a Medicare Part B uniform, ambulatory patient encounter data system. Such a data system will be required to permit the efficient "focusing" of PRO review on identified suspicions of inappropriate or poor quality care in the ambulatory setting. Reliance on "random" review of physician office records will be expensive, intrusive, politically volatile, and AMPRA believes, non-productive.

I, once again, want to thank you on behalf of AMPRA for your tremendous support of the PRO program and your leadership in legislating the expansion of PRO authority beyond the hospital door. Please let me know how AMPRA can be of assistance in the future.

Sincerely,

Andrew Webber

Andrew Webber
Executive Vice President

Item 3

Ocala Eye Surgeons

1500 South Magnolia Avenue, Ocala, Florida 32671
Telephone (904) 622-5183 (800) 342-2530

Donald L. Smith, M.D.
Gordon C. Schwenk, M.D.

May 19, 1988

Nancy Smith
Senate Special Committee on Aging
G-41 Dirksen
Senate Office Building
Washington D.C. 20510

TESTIMONY FOR MAY 23, HEARING

Dear Ms. Smith:

The enclosed items reflect our increasing concern as eye surgeons about the questionable practices of Medicare paying non-surgeon optometrists to follow cataract surgery patients. It is a practice which legitimizes kickbacks to optometrists by a handful of so-called cataract "specialists" and which diminishes the quality of eye care to patients.

Patients from our area of Florida, for example, are referred by several local optometrists to cataract surgery centers as much as 90 miles away. Free minibusses shuttle these unwary senior citizens to their destinations, where some spend the night in motels owned by the eye surgeons. In the morning they have surgery, then return on the bus, never to see their surgeon again. The optometrist who referred them follows them through the recovery process and is reimbursed by Medicare.

We see the unfortunate minority who are victims of this patient factory; some whose astigmatism resulting form surgery has developed unchecked; some who have iris material or lens debris in the lens sac; others with damage to the posterior lens capsule. Most are victims of assembly line surgery whose postoperative follow-up failed to detect ensuing complications early enough to prevent visual impairment.

Last October, we began a campaign to encourage people to seek second opinions. Since then, we have seen people already scheduled for surgery whose vision was correctable to 20/20 with eye glasses, people whose vision loss was less than the guidelines for surgery set by the American Academy of Ophthalmology and others who would be placed at risk by cataract surgery. Unfortunately, some of these people have not heeded our advice to forego surgery, only to return with poorer vision than they had before.

From a financial standpoint, cataract surgery is a cornerstone of most ophthalmology practices. For most patients, Medicare funding is essential. The current Medicare rules, however, have encourage reckless risk of patients' eyesight by making it profitable for optometrists to align themselves with high volume cataract "specialists" in exchange for the follow-up billings. Surgeons who care only about the dollar volume of their practices are only too happy to shift follow-up patient responsibilities to those who keep the assembly line flowing. Those doing the follow-up, unfortunately, lack the qualifications to even understand how unqualified they are.

Although this may sound like we are just trying to "protect our turf", we actually are much more interested in our patients' benefit. We can see no reason why anyone should travel great distances to undergo cataract surgery when it can be performed just as well in almost every community in the United States at far less expense to the patient and/or the patient's insurance carrier.

Sincerely,

Gordon C. Schwenk, M.D.

GCS/bha

Enclosures

Ocala Eye Surgeons

1500 South Magnolia Avenue, Ocala, Florida 32671
Telephone (904) 622-5183 (800) 342-2530

Donald L. Smith, M.D.
Gordon C. Schwenk, M.D.

" Copy "

Melvin Seek, M.D
2980 S.E. 3rd Court
Ocala, Florida 32671

Dear Dr. Seek:

Unnecessary surgery of any kind is intolerable and unethical, but when elderly citizens are the unwary prey, it becomes the responsibility of professionals in the affected field to prevent further abuses.

Responsible ophthalmologists everywhere are concerned by a growing number of unwarranted cataract surgery cases. Breakthroughs in the use of intraocular lens (IOL) implants to replace cataractus lenses have resulted in miraculous restoration of vision, but the speed and relative ease of this procedure have also led to abuses.

Numerous ploys have been and are being used daily to convince elderly people to submit to unnecessary cataract surgery. In some cases, elderly from our area are provided free transportation to distant services, ostensibly for an initial visit. Feeling under some obligation, many are convinced to have their surgery the same day.

Ironically, unaware victims are usually pleased at the clear vision provided by their new IOL implants. However, as you know, all surgery carries risks. The risk that even one person's vision could be lost or reduced by unnecessary surgery is unacceptable.

That is why **The Ocala Eye Surgeons** have decided to support our state society president (his message is attached) in his call to take a stand against unnecessary cataract surgery, and why we are advising you of our actions. We are initiating a campaign to encourage all potential cataract surgery patients to **Get A Second Opinion.**

As board certified ophthalmologists, we will provide second opinions at no expense to patients by accepting assignment from Medicare or private insurers.

In addition, we are sending this mailing to all MD's in the Ocala area. We are sending similar information to our former patients, so that they might advise their spouses and friends. We are also placing public service advisory messages in area Yellow Pages, and we will be taking this message to senior citizens' gatherings wherever we can.

You can help protect your patients by advising them never to let anyone pressure them into cataract or other eye surgery. If you would like more information regarding either cataract surgery or our campaign for second opinions, please feel free to call.

Sincerely,

Donald L. Smith, M.D. Gordon C. Schwenk, M.D.

DLS/GCS/kr

Enclosure

THE OCALA
EYE SURGEONS

Donald L. Smith MD
Gordon C. Schwenk MD
Medicare Participating
Physicians
Board Certified
Ophthalmologists
622-5183
1-800-342-2530

HERE'S LOOKING AT YOU!

FALL 1987

Dear Friends,

"GET A SECOND OPINION"
CAMPAIGN BEGINS

With this letter The Ocala Eye Surgeons are beginning a campaign against unnecessary eye surgery, a campaign to encourage all eye-care patients to seek second opinions. To support this effort, we will provide second opinions for whatever each individual's insurance will pay, with no expense to the patient.

Specifically, we are joining a growing number of ophthalmologists nationwide who are concerned that many unwarranted cataract surgeries are taking place. The president of our Florida Society of Ophthalmologists said recently, regarding unnecessary cataract surgery, "We as physicians and ophthalmologists must remain the watchdogs of our profession....We must not allow dubious ethical practices of some of our colleagues to harm patients. We must actively pursue the high ethical standards with which we began our journey in medicine."

Just because you have a cataract is not reason enough to have a cataract operation. Many people can function for years with little loss of vision from their cataracts. Yet, every year, hundreds of unwary people become cataract surgery patients ahead of their time. Often, they are pressured to make an immediate decision. One Ocala woman, for instance, was recently told by an out-of-town surgeon to be prepared for surgery on the day of her initial visit.

This is happening because cataract operations have supposedly become "simple," and because the improvement in vision that usually results is so dramatic. Just 10 years ago, cataract surgery was something to dread. In fact, it was considered a last resort. Patients had to lie in bed for days following surgery, their heads held motionless by sandbags. After a slow recovery, the best they could look forward to was obscure vision, distorted by thick, "Coke-bottle" eyeglasses.

Invention of the Intraocular Lens (IOL), a piece of plastic not much bigger around than a pencil eraser, changed cataract surgery forever. Today, a competent surgeon can remove a cataract-clouded lens and replace it with an IOL in less than an hour. Patients can have their surgery early in the morning and be home by lunchtime the same day. Vision starts to improve the following day, when bandages are removed, and most patients can see better after a few days than they have in many years.

For an unfortunate few, however, vision worsens or is lost after surgery. Infection sometimes sets in. Bleeding or retina detachment may develop. The truth is, many complications could be avoided if second opinions became routine. In addition to preventing unnecessary operations, second opinions can only improve the chances of identifying high-risk patients before surgery.

The Ocala Eye Surgeons endorse modern implant surgery. In fact, as Ocala's only Board Certified eye surgeons, we use the latest techniques to perform most of the cataract operations in this area. But when should a cataract-clouded lens be replaced with an IOL? The answer varies with each patient, though we know it is no longer necessary to wait for the cataract to "ripen." Some patients should have surgery sooner than others. If their work or other interests require keen eyesight, early cataract removal may be necessary.

The main point is this: Cataract surgery is not "simple," no matter what anyone tells you. All surgery carries risks, and eye surgery is no exception. No one should rush into cataract surgery on a spur-of-the-moment decision. It isn't like buying a new dress or hat.

We encourage you, your spouses and friends to do as our new public service message in the Yellow Pages will advise: "Open Your Eyes (You Have Only Two)...and Get A Second Opinion!"

**THE OCALA
EYE SURGEONS**

Donald L. Smith MD
Gordon C. Schwenk MD
Medicare Participating
Physicians
Board Certified
Ophthalmologists
622-5183
1-800-342-2530

SPRING 1988

HERE'S LOOKING AT YOU!

Dear Friends,

CATARACT CAMPAIGNS HEATING UP

It's that time again. Everywhere you look a politician is trying to sell you his services. This year, something else has been added. Next to the politician's campaign ad is one from someone who wants to pluck out your cataracts.

This year, more than ever before, you are seeing expensive television commercials and colorful advertisements selling the services of cataract "specialists." Many of those you see advertising have given up the broader practice of ophthalmology to concentrate primarily on cataract removal. These doctors have chosen to concentrate on the most lucrative part of the field. Some of them even advertise "free" surgery to entice new patients. When you get there, you usually find out that "free" means they accept Medicare assignment, just like most other doctors. No one spends thousands of dollars on advertising just so they can work for free.

Cataract surgery is one of the most reliable, safe operations available today. A patient can walk in for surgery in the morning and be home in time to watch the afternoon soap operas. "Magical," "miraculous," "unbelievable" are the words patients most often use to describe the improvement in their vision created by a modern cataract operation. From a patient's point of view, words can't express the gratitude most of them feel for the doctor who has restored their eyesight. From an eye surgeon's point of view, removal of cataracts is the most profitable kind of eye surgery today.

It takes a great deal of knowledge and skill to perform cataract surgery. If you think "knit one, pearl two" is close work, try tying knots (stitches) with thread thinner than human hair under a powerful microscope. But similar delicate skills are required for laser surgery, for correcting "crossed" eyes, and for all the other services ophthalmologists perform.

The Ocala Eye Surgeons continue to provide a complete range of eye care and eye surgeries, using the most modern equipment, facilities and techniques. We do no advertising, except in the yellow pages. Call us old fashioned, but we still rely on you, our current and past patients, to spread the word to new patients. We've built our reputation one patient at a time, and that seems to be working for us.

Item 4

NORTH CAROLINA STATE BOARD OF
EXAMINERS IN OPTOMETRY

June 20, 1988

Senator John Heinz
Russell Senate Office Building
Room 277
Washington, DC 20510

Dear Senator Heinz:

At its meeting on June 4, 1988, the North Carolina State Board of Examiners in Optometry reviewed the testimony of Walter Wright, M.D. of Kinston, North Carolina (appendix 1), given before your committee, the Senate Special Committee on Aging, on Monday, May 23, 1988, in Philadelphia. The Board was also presented with copies of the written testimony as submitted by the other witnesses whose names appear on the enclosed witness list (appendix 2), as well as a transcript of the NBC TV May 23, 1988, the Today Show on which you were interviewed (appendix 3).

Based upon its review of the testimony before your committee, the Board assigned its special counsel, Eugene Boyce of Womble, Carlyle, Sandridge and Rice, to investigate matters of substance arising from information relative to conduct by licensees of this Board which if true involve probable violations of state or federal law or the duly adopted regulations of this Board.

While we intend to investigate all of the allegations made in Dr. Wright's testimony, as well as the material contained in the "casebook" he presented and which you accepted as part of record of the hearing, the Board determined that its special counsel should concentrate his efforts initially on the allegations by Dr. Wright as contained in paragraphs 3, 5, 9, 11 and 12 of his testimony (appendix 1). We will share our investigation results with the N. C. State Board of Medical Examiners insofar as medical doctors are involved.

It should be made clear for the record that your reference to "turf fights at the state level between the boards of ophthalmology and the boards of optometry" on The Today Show (appendix 3 page 2) is incorrect. There are no state boards of ophthalmology. Ophthalmologists, as physicians, are licensed in every jurisdiction by the state board of medical examiners in the same manner as are all physicians and are granted the same license. There is no specialty licensing of medical doctors by any state for any of the medical specialties. Optometrists are licensed in the practice of optometry by the state board of optometry in every jurisdiction. Further, in most if not all jurisdictions, those persons licensed to practice optometry are exempted from the practice of medicine in the practice of optometry and those persons licensed to practice medicine are likewise exempted from the practice of optometry in the practice of medicine.

The confusion of state boards aside, this board would like to take issue with your statement on the Today Show that the "federal government has to step back in and do what the state boards are basically unable to do, and that's set these standards". In the State of North Carolina, there is a standard consistent with quality of care in cataract surgery as well as in post-cataract surgery care and following. We submit that there is a policy that addresses an acceptable standard of care that involves post-operative care and following of cataract surgery patients by optometrists that is consistent with quality of care that has evolved over the past number of years that has been ruled upon by the North Carolina Board of Medical Examiners, the North Carolina State Board of Examiners in Optometry, the Attorney General of North Carolina, and the Health Care Financing Administration. Further, these standards are consistent with applicable federal and state law that govern the practice of medicine and the practice of optometry; the reimbursement for services of both physicians and optometrists; and the federal and state freedom of choice laws.

We are enclosing for the record the following documents to substantiate the fact the issues raised by the participation of optometrists in patient care, particularly as this participation relates to pre-surgery diagnostic examinations and the post-surgical care and following of cataract surgery patients have been addressed by the proper regulatory authorities and an agreed upon standard of care ruled upon:

1. Letter of Bryant Paris to Eugene Stead, Jr., M.D. dated September 5, 1985 relative to a motion adopted by the North Carolina Board of Medical Examiners relative to the "view" of the Board on post-operative care and following of cataract surgery patients (appendix 4).

2. Letter of John D. Robinson, O.D., Secretary of North Carolina State Board of Examiners in Optometry, to Bryant Paris dated September 19, 1985 (appendix 5).

3. Letter of John D. Robinson, O.D., Secretary of North Carolina State Board of Examiners in Optometry, to Bryant Paris dated October 4, 1985 (appendix 6).

4. Letter from North Carolina State Board of Examiners in Optometry to all licensees dated October 10, 1985 (appendix 7).

5. Ruling by North Carolina Attorney General relative to "optometrists, post-operative care of cataract surgery patients, practice of medicine" dated August 6, 1986 (appendix 8).

6. Consent Order entered by the North Carolina Board of Medical Examiners and agreed to by Steven M. White, M.D. on September 13, 1987 and signed early October, 1987 (appendix 9).

7. Memorandum from the Board of Optometry to N. C. licensed optometrists and other interested parties relative to post-operative care and following of cataract surgery patients dated March 16, 1988 (appendix 10).

We would urge that you and your staff carefully read and review these documents along with the testimony given before your committee May 23 and particularly that material submitted in the "casebook" submitted by Dr. Wright and its covering preface which bore the names of Scott P. Bowers, M.D. and Walter Wright, M.D. as the signators. You should particularly review the charges and threats of litigation contained in Dr. Bowers' letter to Mr. A. P. Walsh at Prudential Medicare dated February 5, 1986 which was a part of this casebook.

Additionally, we have been furnished a video tape of Dr. Bowers' testimony before the Senate Consumer Protection and Professional Licensure Committee of the Pennsylvania legislature in late July or early August 1987 when he appeared in opposition to the bill that would allow the use of therapeutic drugs by optometrists in the State of Pennsylvania. Following his testimony and questioning, Senator John Shoemaker, a member of the Committee, asked Dr. Bowers if he would submit documentation as substantive evidence to support the allegations made in his testimony before that Committee, particularly as the testimony related to unnecessary surgery, malpractice litigation and other charges of alleged unlawful or unethical conduct by both physicians and optometrists in the State of North Carolina. Enclosed is a letter dated August 27, 1987, from Dr. Bowers to Senator John Shoemaker (appendix 11), which this Board received on September 17, 1987. This letter like the preface to the casebook attempts to explain away the lack of documentation or credible evidence to support the allegations of unlawful or unethical activities. To the best of our knowledge, the Senate Consumer Protection and Professional Licensure Committee has not been furnished any additional information or any "valid and verifiable statistics regarding the rate of medical malpractice among high volume surgeons" referred to in Dr. Bowers' letter.

We would like to state for the record that Dr. Bowers has a long and continuing record of publicly presenting allegations of fraud, kickbacks, mismanagement, malpractice, unnecessary surgery and other unlawful behavior on the part of both ophthalmologists and optometrists without supporting documentation or witnesses. We have not been able to document any of these charges or allegations made over a period of several years as substantive or truthful at this point in time. Our special counsel, Mr. Boyce, is currently engaged in taking depositions as a result of public allegations made in a malpractice law suit that has been filed wherein an optometrist is alleged to have knowingly participated in the referral of a patient for unnecessary surgery. Dr. Bowers is one of several physicians he wishes to depose in this matter given clearance by the Courts on an issue of patient-doctor confidentiality that has been raised by the attorney for the plaintiff who alleged that she had unnecessary surgery.

Finally, we would like to express our concern at your apparent willingness to accept as fact and to express an opinion that quality of care, as its relates to cataract surgery, can be quantified by simply declaring that if the optometrist is limited in the referral as well as the post-operative following, and the ophthalmologist excludes optometric participation in the care of the patient for some unstated period of time, then quality of care is somehow assured or enhanced. You seem to be saying that in the instance where the optometrist is involved in that patient's care immediately prior to or shortly following surgery, that this indicates an inappropriate standard and a poor quality of care. In our opinion you could not be more wrong. Neither you or the federal government will ever be able to address quality standards by such arbitrary means.

No one should be more interested in the successful outcome of a surgical procedure - thus the highest standards of quality of care - than is the optometrist who makes the referral. It is he who puts his professional reputation on the line within his practice and his community whenever he makes a referral - whatever the reason. Poor surgical results or compromises in good patient care as could be evidenced by incompetent post-operative follow-up care would have just as a disastrous effect - if not more of an effect - on the optometrist's practices than on the practice of the ophthalmologist. And, we would hasten to point out, that there can be no legitimate claim by Dr. Wright or Dr. Bowers or Dr. Stokes who testified for the American Academy of Ophthalmology that ophthalmology is any more interested in good patient care than is optometry. Economic incentives that are provided by the system of reimbursement can lead an individual to place his or her economic welfare above that of the patient. Unfortunately, there are those who exploit both the system and the patient and it is our duty to weed them out. We accept this responsibility.

Our interest in quality of care and acceptable standards of practice is ongoing and we have no problem with objective and unbiased studies that would fairly evaluate what is happening today in the field of eye care, particularly as it relates to the issues of alleged kickbacks or the quality of care of patients. However, any study that is made should encompass a review of patients who have been operated upon by a broad sampling of ophthalmic practices, that would include both "high volume", "mid volume", and "low volume" surgeons; and those who do all the post-op following and those who don't, but rather refer the patient back to the referring optometrist for follow-up care. We would submit that initial studies could be done effectively and affordably by simply reviewing Medicare reimbursement claims for a range of cataract surgery patients over the past three or four years with a special look at those patients who have had secondary and tertiary surgeries that could indicate complications or problems with the initial surgery. The number and types of complications should be evaluated in both "high volume", "mid volume", and "low volume" surgical practices. To us this would be a feasible method to at least begin to quantify "quality of care".

The committee should be interested in the surgical statistics we obtained from Prudential Medicare (appendix 12) a year ago relating to the number of cataract surgeries in North Carolina in 1985 and 1986. These figures are especially significant if one will accept the fact that extracapsular cataract extraction (procedure code 66984) with IOL implant is now considered the state of the art, thus the acceptable procedure that is performed on the vast majority of patients today. With extracapsular extraction being the accepted standard then the intracapsular cataract extraction has become an inappropriate standard of care in all but the small minority of cases where extracapsular surgery might be contraindicated. Historically it should be noted that in the early 1980's only a hand full of surgeons in this state and relatively few in the nation were doing the extracapsular procedure with the posterior chamber implants. These surgeons were the pioneers in implant surgery and the first to develop a high level of skill in performing the procedure. In this period covered by Medicare statistics in North Carolina without significant change in either the total numbers of cataract surgeries or in the numbers of surgeons doing cataract surgery in 1986 and 1987, the total number of each procedure , i.e. intracapsular vs. extracapsular changed dramatically with the intracapsular procedure dropping from 17,459 in 1985 to only 1753 in 1986 while the number of extracapsular surgeries dramatically increased from 6,865 in 1985 to 23,630 in 1986. Prudential Medicare was unable to determine how many of the extracapsular procedures represented patients with posterior chamber implants vs. those with anterior chamber implants; however, the number could be quite revealing. The early anterior chamber lenses were easier for the inexperienced or lesser skilled surgeon to implant but the risk of complications is much greater. It was fairly apparent early on in implant surgery that the posterior chamber implant was superior and offered a significantly less chance of complications in the long term.

Since it is universally acknowledged that the surgical skill necessary to perform extracapsular surgery with a posterior chamber implant is greater than that needed for the earlier more frequently performed intracapsular surgery with or without a lens implant, one must be curious as to how fast these skills were acquired in this state by so many surgeons.

Senator, you are correct when you refer to the controversy between ophthalmology and ophthalmologists and between ophthalmology and optometry as "turf battles" and we have no problem with this terminology in the strictest sense of the term. The fact is that optometrists are providing an expanding range of services and care to patients and in areas that were traditionally looked upon as the province of medicine. We are in an era of vastly expanding knowledge and technology and optometry is very much a part of this expansion. If we moved back a mere 20 years, 80 to 90 percent of the armamentarium utilized in the health delivery system today would not be available.

We would respectfully ask that this letter and its enclosures be made part of the record of the hearing before the Senate Committee on Aging. If there are questions or if you need additional information following your review of the submissions on the part of the Board, please feel free to contact me at the address below. –

For the North Carolina State Board of Examiners in Optometry, I am

Sincerely,

John D. Robinson, O.D., Secretary
P. O. Drawer 609
Wallace, N.C. 28466
(919) 285-3160

Enclosures

cc: Board, Attorney, Special Counsel
NCSOS Officers, Trustees
AOA Officers, Trustees
IAB Officers, Board of Directors

Item 5

Ωmega Health Services, Inc.

June 20, 1988

The Honorable John Heinz
Ranking Member
U. S. Senate Special Committee of Aging
628 Hart Building
Washington D.C., 20510

Dear Senator Heinz:

Enclosed is testimony for the field hearing on Kickbacks in Cataract Surgery. There are separate statements from James A. Bruce, M.D. who is our National Medical Director and from Allen J. Blume, O.D. and myself.

We welcome this opportunity to provide testimony for the record and believe that you will find our viewpoint somewhat different from those previously obtained. If there are additional questions, please contact us.

Thank you.

Respectfully yours,

Robert Qualls
President and
Chief Executive Officer

RQ:jai

Enclosure

TESTIMONY FOR THE RECORD

JAMES A. BRUCE, M.D.

I am James A. Bruce, M.D., an ophthalmologist in practice in Jackson, Mississippi. After reviewing the testimony given your committee in Philadelphia, I find my experience with a practice management company fundamentally different from the view you received at that meeting. For this reason I appreciate the opportunity to present my view of Optometry and Ophthalmology and how their relationship affects illegal activity. The interface between Ophthalmology and Optometry is a complicated interaction of two health care disciplines which have overlapping interests. Hard feelings, poor communication, and misunderstanding have been rampant on both sides. I feel this hostility causes some patients to receive less than optimal eye care.

In 1935 organized medicine declared any relationships between ophthalmologists and optometrists unethical. The subsequent history of competition, misunderstanding, and open warfare is familiar to all of us. The recent battleground has been in the state legislatures with optometry trying to expand its practice scope through legislation. The lack of clear cut lines of communication, varied state laws, and Governmental involvement have further increased conflicts between the professions. Most Ophthalmologists feel Optometry lacks adequate training and is trying to legislate itself into the practice of medicine. However, we in ophthalmology have been guilty of impeding the educational interchange between ophthalmology and optometry. Any formal association with optometry causes one to be ostracized. A more realistic educational system would encourage mutual respect for each profession's unique abilities. I feel this would stimulate a more rational referral system. Most people agree Ophthalmologists are the logical group to provide secondary and tertiary eye care. However, Optometry is a well founded profession and represents a valuable national resource. Rightfully utilizing optometrists as primary eye care providers in our national health care system would benefit the patient population of this country. I feel the proper use of this resource is being jeopardized by the actions of the fanatics of both sides.

The optometric profession is presently improving the educational curricula to include more diagnostic and treatment services. They will continue to try to enlist the aid of ophthalmologists in teaching the heart of Ophthalmology: examination, evaluation, and diagnosis of patients with eye disease. More states allowing the use of diagnostic and therapeutic drugs will probably stimulate them to adopt new responsibilities. It might even lead to redefinition of the practice of optometry to include areas now considered the province of medicine. At present any ophthalmologist trying to help with the education of optometry is ostracized completely from the ophthalmic community. A recent Harvard study found that our population is aging. At present there are 29,000,000 people over age 65 in the United States. This group will grow to 39,000,000 in the year 2000. I understand that 70% of eye care professionals in this country are optometrists. They care for at least 50% of all eye patients. This, in conjunction with ophthalmology logically providing the secondary and tertiary eye care, makes it imperative, in my view, to develop a better relationship between ophthalmology and optometry.

Presently a maldistribution of eye care professionals exists with the concentration of ophthalmologists in cities and optometrists in smaller towns. Optometry and ophthalmology are now faced with corporate competition. Attempts to squeeze organized medicine occurs from the "alphabet" groups --IPA's, HMO's, etc. These changing economic facts, the erosion of the patient base, and government encouragement have led to increased competition. In this environment any relationship involving optometry and ophthalmology is immediately suspect by militants on both sides. I believe successful relationships between ophthalmologists and optometrists are those based on mutual respect and are not simply on economic gain. Most surgeons still gain large referral bases by surgical excellence. Their tendency is to treat the referring doctor with the respect due another professional and not the condescending manner most ophthalmologists encourage.

Optometry and Ophthalmology are presently on a collision course. It is my contention that time is running out for the cooler heads in the two professions to make an accommodation. With this in mind, I decided to associate myself with an effort to change the aura of hostility, misunderstanding, and poor communication. In addition I hoped to expand myself professionally, personally, and economically.

This brings me to Omega Health Systems, a management company, and my association with them. Our purpose is to demonstrate that a close, truly ethical, working relationship between ophthalmology and optometry can occur beneficially to all parties. Remember, at least 50% of patients enter the eye care system through Optometry. I simply can't advocate a system which withholds important information in an attempt to hold a profession hostage thus jeopardizing patient care. However, I also can't heartily support a system allowing legislative upgrading without educational preparation for the increased responsibility. The patient must come first - anything less and we will fail. I believe many ophthalmologists would help improve the educational opportunities for optometrists if professional isolation didn't result. I believe the distorted view of the proper relationship between ophthalmology and optometry comes largely from people speaking in their own self interest.

Although I too can not eliminate all bias, I sincerely believe I am presenting another legitimate side of the argument. My experience with Omega Health Systems is much different from that experienced by Dr. Pomerance with his management company and practice. I too have a managed practice (by Omega Health Systems), an optometrist in practice with me, and an optometric resident. We have about fifty to sixty referring optometrists. I had similar experiences with the organized ophthalmic community when I opened this practice. From this point on, however, our experiences diverged dramatically. My contract specifies that all decisions involving medical care, scope of practice, and specific care is not only my right but my direct responsibility. I, and I alone, choose the site of care for all patients limited only to a certified medical facility. No one has ever tried to influence this process in the two years of my association. The optometrists that I have dealt with seek optimal care for their patients and economic considerations aren't the pivotal factor in their referral. Many of the investors in our clinic have not sent any patients to our clinic in the two years of operation. The complaints I receive are typical of a referral practice. None have involved the type of interferences cited by Dr. Pomerance in his experience with his group. I feel he became isolated through his own actions instead of being the victim of any devious system. He abandoned his practice without notice to anyone, including patients and referring doctors. I suggest he should expect the whole medical community to have doubts on his dependability after this action regardless of grievances. Appropriate notice to patients, workers, management, and referral sources seems mandatory in the medical care field.

While I personally believe that many optometrists are competent to recognize post-op complications, the surgeon has specific responsibilities which supersede other considerations. The patient deserves to expect the surgeon he chooses to supervise his pre-operative care, surgery, and recovery. Specifically, I select the surgical timing, choose the implants, make the surgical decisions, and develop the treatment plans for our patients. Omega Health Services expresses no expertise in the area of medical treatment and exerts no influence on my decisions in this area. In our routine the patient returns to my clinic for follow-up on the first post-op day, the first week, the sixth week, the third month, and any other time his post-op recovery would indicate. Some of the referring optometrists choose to see the patient on the third and ninth week visit. Some choose for us to perform all post-op care. We had one patient recently who developed pain in the ninth post op day and demonstrated the integrity of our concept. He initially called his local optometrist, a long time friend, because he had a long term good relationship with him. This optometrist, having received post-op care courses from us on several occasions, immediately recognized that endophthalmitis was a possibility. He virtually forced the patient to come to our clinic at eleven o'clock that night. Our optometric director called me immediately after examinig the patient. I evaluated the patient and instituted the appropriate therapy for the patient. Our preparation and education worked as envisioned in our network.

We can empathize with the patients presented to your committee who lost their eyes to endophthalmitis. It is unfair, however, to indict an alternative health care system on this unfortunate occurrence often uncontrolled in spite of all therapy. Endophthalmitis is a devastating occurrence in eye care. Any truthful ophthalmologist will report that it is difficult to control, often relentless in its progression, and destroys most eyes in spite of timely diagnosis and treatment.

In the late seventies and eighties the government set in motion a series of events to stimulate competition in medical practice. While some abuses have obviously developed in the system, it has been overwhelmingly good for the public. We have just begun to rely on specialization and teamwork for more efficient care. Of course this requires skillful and well trained team players. Presently many alternative delivery systems are being tested. We must evaluate them without prejudice to establish which system preserves fundamental ethics (good patient care) without regard to economic return. We are indebted to the entrepreneurial ophthalmologist for showing us that secondary level care can be efficient, cost effective, and appreciated by the patient. Surgeon performing the most surgery usually are more proficient than the occasional operator. In 1984 some predicted that the "high incomes" generated by "high volume" surgeons would result in the lower fees for cataract surgery. We have seen reductions in cataract fees in both of the last two years. Unfortunately, this does have a devastating economic effect on low volume surgeons. The outrage intensifies when the ophthalmologist with a more traditional, less surgically oriented practice, loses his surgical and referral base to those who are trying to accomplish a successful interface between ophthalmology and optometry. This causes him to develop a distorted outlook on any alternative delivery system.

Anytime a financially lucrative field is in turmoil a few charlatans will step in and use the opportunity for profiteering. However, many traditionalists are using this as an excuse to recommend stifling the growth of any alternative health care system. If they accomplish this goal, those disposed to illegal or abusive behavior would still be able to abuse the traditional system. A crooked physician is no different from any other crook. In my estimation we should prosecute those abusing the system by activities clearly illegal, such as double billing and billing for procedures not performed. We do not try to stop trading stocks on Wall Street because we find a crooked broker.

The technical advances in ophthalmic surgery accelerated after the Federal Trade Commission encouraged entrepreneurial activity a few years ago. During this time, when financial rewards were present for successful entrepreneurs, we have seen a marked technical advance in ophthalmology. For years those already established in medicine have tried to make it very difficult for advances to occur. An example is the intraocular lens. This fantastic device was first implanted in England in 1948 by Sir Harold Ridley. The technology smoldered until the mid seventies when a few entrepreneurial ophthalmologists in the United States espoused it. In its early development, traditional ophthalmologists criticized anyone using these devices. Now over 95% of eyes receive intraocular lenses after cataract surgery. Now almost all are now done as outpatients and in 1973 the hospital stay was usually a week. Lasers, phacoemulsification, and refractive surgery are other examples in which early users suffered abuse. My point is that often organized medicine overstates the negative motivation of those exploring new vistas.

I certainly hope you will address only those truly abusive practices and give us a better definition of legal and ethical behavior. You can get no one to define legal and ethical boundaries except those with severely biased positions. In a similar vein an undefined atmosphere of acceptability in the area of marketing, practice management, networking, and other areas of professional interaction leave the programs open for abuse both intentional and unintentional. Hopefully, programs like ours encouraging close cooperation between ophthalmology and optometry will initiate respect and understanding between these professions. I sincerely hope no official blockades will be instituted. Today health care is very costly to this country and is a big business (10% of the gross national product). Health care has become a primary target for expense reduction by the government precisely because of this. We should encourage honest competition, even though many of us might suffer in the beginning, because it ultimately produces the best system.

Given the many forces, both external and internal, exerted on the two professions, is it possible to develop an eye-care delivery system that establishes and recognizes a role for the optometrist and the ophthalmologist? Obviously, it will not be an easy task, but I believe cooperation and education make it possible and desirable. Thank you for allowing me the opportunity to include my thoughts on this subject.

TESTIMONY FOR THE RECORD

MR. ROBERT QUALLS, PRESIDENT

ALLEN J. BLUME, O.D., NATIONAL OPTOMETRIC DIRECTOR

OMEGA HEALTH SYSTEMS, INC.

7770 POPLAR AVENUE

SUITE 105

GERMANTOWN, TN. 38138

TESTIMONY FOR THE RECORD

OMEGA HEALTH SYSTEMS, INC.'s perception of the problems associated with Medicare Reimbursement for Post-Operative Services following Cataract Surgery is based on our viewpoint as a management company involved in the ophthalmic surgery business. We maintain the basis of the current problem relates directly to historical events that have occurred within the professions.

OUR COMPANY

OMEGA HEALTH SYSTEMS, INC. (OMEGA) is in the business of managing the practices of ophthalmologists. Surgical and medical ophthalmology is provided at Omega managed "centers" with primary vision/eye care provided by referring optometrists. The company's activities involve the coordination of both optometric and ophthalmological services to establish an integrated eye care system that provides quality primary, secondary and tertiary care efficiently and cost effectively.

Omega's managed practices are beneficial for ophthalmologists, optometrists and their patients. Ophthalmologists provide medical ophthalmology and ocular surgery without the burden of routine primary eye care. This allows the surgeon to practice ophthalmology at it's highest level. Optometrists enjoy dependable, quality medical and surgical support while working in a cooperative manner with ophthalmology. In our system the real beneficiary is the patient. They are provided a total eye care program which is carefully monitored through all stages of treatment. Additional benefits include lower cost for quality care and less disturbance of the patient's normal routine.

In Omega Eye Care Centers network optometrists are under no obligation to refer to the center. In most centers there are optometrists who do not use the center's ophthalmological services. On the other hand, there are some network optometrists who refer exclusively to the center. In our experience, proper patient care has been the foremost consideration demonstrated by our network optometrists.

All medical decisions are the sole responsibility of the surgeon. The ophthalmologist has the first and last word in reviewing any preliminary diagnosis and in selection of appropriate treatment or surgery. This right and responsibility has never been questioned by either Omega Health Systems, Inc. or the referring optometrists at any of our centers.

Regarding post-operative care, network optometrists in our centers participate to varying degrees based of mutual agreement between the surgeons and referring doctors. Our ophthalmologists are under no obligation to permit referring optometrists to provide post-operative care. None of our network optometrists are involved in post-operative care until they have completed the necessary training and review by the attending surgeon. Our education and training procedures involve lecture and grand rounds participation at the clinics to insure adequate clinical exposure to specific post-operative complications. These educational efforts are designed and implemented at each center by the medical director (ophthalmologist).

BACKGROUND

Historically, ophthalmology and optometry have been involved in "turf battles" and economic conflicts. This confrontation developed in part due to areas of overlap in the services they provide. Due to the nature of each profession's individual services optometry has served as the major medical/surgical referral resource for ophthalmology. Traditionally, ophthalmology has been inclined to treat referral relationships with optometry in either a disrespectful or unprofessional manner. Many ophthalmic surgeons accepted referrals from optometrists while at the same time treating optometry in a disparaging fashion. This in is contrast to the prevailing attitude in normal referral relationships between other health care providers where the consulting physician supported the referring physician in the most professional manner possible. The mutual support and respect between referring doctors who share in the care of patients has never been referred to as unethical or illegal. In fact cordial and cooperative intra-profession referral has been the most effective, integrated and efficient method of providing total care. This type of referral relationship did not have an opportunity to develop between ophthalmology and optometry because ophthalmology refused to accept optometry as a legitimate health care profession.

The referral relationship between the eye care practitioners varied from a very professional interaction to outright refusal to acknowledge or respond to referrals. This has been manifested in many cases by a condescending attitude on the part of the surgeon. Some militant surgeons in this confrontation resorted to badgering patients suggesting they should not have consulted an optometrist initially. In most cases ophthalmology has been inclined to treat the consultation as a terminal referral. Many have been unwilling to return the patient to the referring optometrist following treatment. Rather the surgeon was often inclined to suggest they should provide all subsequent primary care themselves. The resulting loss of the patient by the optometrist has further heightened the climate of mistrust and suspicion on the part of optometry. Furthermore, ophthalmology opposed any improvement or expansion in the role of optometry in the health care system delivery system. In spite of this opposition optometry has successfully expanded it's role in the eye care arena. Optometry has gained the legal privilege to diagnose and treat eye disease in 23 states. Current trends suggest this re-definition of optometry will continue and ultimately will be universal in all states. Optometry's expansion has resulted in increased ophthalmological concern with the goals and aspirations of optometry. These events have further increased the dissension between the two professions, particularly in the minds of the more militant members of each group.

Concurrently, there has been a surplus in the production of ophthalmologists and optometrists exceeding the increase in the aging population. This results in a decrease in the number of patients per eye care practitioner thereby increasing the competitive pressures both within and between the professions. Coupled with the surplus of eye care practitioners, historical "turf battles" and mutual distrust, there have been dramatic technological advances in eye surgery. This has altered the manner in which cataract surgery is viewed by ophthalmologists, optometrists and the general public. These existing factors, combined with an aging population and increased medicare reimbursement, have created the potential for marked changes in the delivery of ocular surgery, particularly cataract surgery.

THE SITUATION TODAY

Specifically, surgeons, optometrists and cataract patients are much more apt to embrace cataract surgery today than 10 - 15 years ago. Before the marked advances in cataract surgery (particularly intraocular lens implantation) the doctors were more hesitant to recommend surgery until visual impairment was quite severe. Patients were also more reluctant to pursue surgery due to experiences related by friends encountering some marked adverse effects associated with such surgery.

With the advent of improved surgical procedures, improved visual rehabilitation following implantation procedures and reduced adverse effects or complications, the visual outcome following cataract surgery has been significantly enhanced. When these events were combined with increased reimbursement for cataract surgery the climate for aggressive entrepreneurial surgeons to develop marketing programs to increase their surgical case loads was complete. The entrepreneurial surgeon correctly identified that traditional ophthalmology/optometry referral relationship and attending injustices shown optometry in the past was an area they could capitalize on and increase their surgical patient base. By developing a professional relationship based on mutual respect and confidence they were successful in correcting the previous injustices displayed by ophthalmology to optometry. In all fairness, OMEGA suggests these entrepreneurial surgeons were prompted by ethical and professional motivation and not simply economic greed. In our opinion these surgeons were motivated to increase their surgical case load in the interest of perfecting and enhancing their surgical proficiency and technique. They were primarily interested in improving cataract extraction procedures and the visual welfare of their patients. Of course increased surgical case loads improved the revenues of their surgical practices.

As these physicians analyzed the medical and surgical market place they correctly concluded that optometry was a viable component in development of a large surgical practice. These individuals reasoned that by treating optometry in a dignified and professional manner the opportunity existed to develop an alliance with the profession. When they recognized optometry controlled approximately 50 - 70% of the primary eye care market it was self-evident optometry was a viable element in their marketing plan. Furthermore, these physicians reasoned that by assisting in the development and enhancement of optometry through support of their educational efforts through residency training, externships and grand round rotations optometry's support would be enhanced.

We contend the motivation in most cases was to improve patient care and enhance the profession of optometry while increasing their surgical revenues. We submit, none of these motivations are necessarily unethical or illegal. All specialty areas within medicine, including ophthalmology have traditionally marketed their specialty to the rest of the medical community by development of referral bases among other medical practitioners. The major difference in the case of optometry/ophthalmology was certain ophthalmologists were now directly courting optometrists via the same professional methods previously reserved for inter-medical referral relationships.

Due to changes within the entire health care delivery system, health care management companies expressed an interest in the area of surgical management of cataract patients. Management companies analyzed the unique nature of existing medical/surgical referral relationships between optometry and ophthalmology. These organizations concluded they could play a role in improving the interface between the eye care practitioners while providing quality and cost effective eye care to large segments of the population. Several management companies have developed formal relationships between selected surgeons and optometrists known collectively as networks. These management companies and their networks have enjoyed varying degrees of success depending on several factors within each market place.

When formal relationships surfaced in competition with informal relationships developed by entrepreneurial ophthalmologists several competitive factors evolved. The most controversial factor and central to this entire issue involved sharing post-operative cataract care between the surgeon and the referring optometrists. Due to the competitive climate both entrepreneurial surgeons and management companies initiated the promotion of post-operative care by optometrists.

The fact HCFA had traditionally bundled the reimbursement for these services in a global fashion allowed the potential for abuse and questions regarding ethical referral relationships. Omega Health Systems, Inc. contends most of the informal as well as the formal networks are designed to operate in an ethical and professional manner where quality patient care and legitimate reimbursement billings are adhered to without deviation or deceit. Unfortunately, there will always be some individuals or groups who take liberties with rules and regulations. Omega Health Systems, Inc. does not and will not endorse or support illegal activities or kickbacks. If individuals or management companies are found in violation of medicare/medicaid fraud and abuse regulations they should be investigated and prosecuted through the courts. It is our conviction that any form of kickback or financial gain used as an inducement for referral can not be condoned nor tolerated.

It is our contention that primary care, including the diagnosis of cataracts, is within the domain of the referring optometrist. Pre-operative evaluation of the patient, including decisions regarding timing of surgical intervention is the responsibility of the attending surgeon. In our opinion, the follow-up post-operative care of the cataract patient may include appropriate roles for both the attending surgeon and the referring optometrist. The decision of who should provide the follow-up care should not be related to turf battles between ophthalmology and optometry. In fact, the question of which professional should provide the post cataract follow-up care has nothing to do with the question of whether or not optometry is either qualified or legally allowed to perform this service. HCFA has ruled as far back as 1980 that optometry could provide post-operative care. In 1986 HCFA's ruling was expanded to include utilization of optometry as a primary physician for all services medically necessary and allowed by optometric statute. The fundamental issue should involve what the patient desires and deserves from their attending surgeon. Omega contends the surgeon has the responsibility to examine their surgical patient the following day and in one week. The surgeon also deserves the opportunity to evaluate the surgical outcome and critique their surgical techniques 6-8 weeks post-operatively. In the interest of maintaining the doctor/patient relationship (referring optometrist and their patient) we advocate the referring doctor examine their patient during their surgical convalescence and perform a comprehensive evaluation, including refraction and prescription of lenses at the termination of the post-operative interval (90-120 days). This has a positive effect for all concerned parties (patient, surgeon and referring doctors). In effect, this reduces travel and expense for the patient while at the same time allows re-establishment of the relationship between the referring doctor and their patient. It also provides ample opportunity for the surgeon to evaluate and discharge their medical and and surgical responsibilities.

CONCLUSION

We suggest the issue of kickbacks in post-operative cataract care is in reality an economic problem within the ophthalmological profession. Militant ophthalmology is trying to identify this as an issue of quality patient care which is inaccurate. There are already adequate and enforceable laws to address illegal kickbacks. There is no question optometrists can provide post-operative care. The real issue is what is in the best interest of patient care. We suggest the issue of post-operative care as previously presented to this committee is in reality, a ruse promoted by some militant ophthalmologists in an effort to reduce competitive factors affecting their current practice volume. While we are sympathetic to ophthalmology's concerns we can not endorse their approach. Rather, we suggest they concentrate on refining their surgical skills, rethinking their professional bias and working in a constructive manner with all members of eye/vision care team. Not only would this cooperation be in the best interest of quality patient care, but it is our conviction this will result in a reduction in total eye health care costs. In addition, we believe a clearly defined and officially supported cooperative interaction between ophthalmology and optometry would reduce the potential for illegal or unethical practices. We submit these militant representatives should concentrate on monitoring their own members and take the proper steps to eliminate undesirable activities within their own profession. They should not attempt to place all the blame on optometry or integrated eye care groups of ophthalmologists and optometrists as the culprits in health care fraud and abuse.

Thank you for the opportunity to present our position on this critical health care issue. Our comments are intended to be constructive and provide helpful insight as you consider this issue. If you have additional questions please contact us.

Respectfully Submitted: Mr. Robert Qualls and Dr. Allen J. Blume

APPENDIX 3.—MATERIAL RELATED TO PATIENT CARE; OPTOMETRISTS VERSUS OPHTHALMOLOGISTS

Item 1

THOMAS E. FITZ, M.D., PRESIDENT
HICKORY, N.C.

JACK A. KOONTZ, M.D., SECRETARY
GREENVILLE, N.C.

BOARD OF MEDICAL EXAMINERS
OF THE
STATE OF NORTH CAROLINA

BRYANT D. PARIS, JR.
EXECUTIVE SECRETARY
SUITE 214, 222 NORTH PERSON ST.
RALEIGH, N.C. 27601
TELEPHONE 833-5321

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ROSE PULLY, M.D., KINSTON
MARTHA KIRKLAND WALSTON, WILSON

September 5, 1985

N.C. BOARD OF EXAMINERS
RECEIVED
SEP 10 1985
IN OPTOMETRY

Eugene A. Stead, Jr., M.D.
N.C. Medical Society Journal
P.O. Box 3910
Duke University Medical Center
Durham, N.C. 27710

Re: Post-operative Care by Optometrists

Dear Dr. Stead:

At its recent meeting, the Board of Medical Examiners adopted a motion to request that the Medical Society publish the following views of the Board in the next issue of the Journal.

> It has come to the attention of the Board of Medical Examiners that there are a growing number of situations in North Carolina in which ophthalmologists have entered into arrangements with optometrists whereby the optometrists refer to the ophthalmologists patients for cataract surgery and that following such surgery these patients are then returned by the ophthalmologists to the care of the referring optometrists for post-operative care and following. Because it is the view of the Board that such post-operative care and following constitutes the practice of medicine, the practice of permitting persons who are not licensed to practice medicine in the State of North Carolina to provide such care is specifically disapproved by the Board.

If you have any questions regarding this matter, please advise.

Sincerely,

Bryant D. Paris, Jr.

Bryant D. Paris, Jr., Executive Secretary
NORTH CAROLINA BOARD OF MEDICAL EXAMINERS

BDPjr:kb/0541K

Item 2

NORTH CAROLINA STATE BOARD OF
EXAMINERS IN OPTOMETRY

September 19, 1985

Mr. Bryant B. Paris, Executive Secretary
North Carolina Board of Medical Examiners
222 North Person St., Suite 214
Raleigh, North Carolina 27601

Dear Mr. Paris:

Thank you for forwarding to our Board a copy of the letter of September 5, 1985, from you on behalf of the North Carolina Board of Medical Examiners to the North Carolina Medical Society Journal. The resolution setting forth the view of your Board is of interest insofar as it relates to the optometrists of North Carolina generally and to the North Carolina Board of Optometry which is charged by law with the duty of regulating its licensees in their practice of optometry.

Although the wording of the motion appears very guarded, the implication is that there are optometrists who, in performing "post-operative care and following" of patients who have had cataract surgery by ophthalmologists, are violating the laws relating to the practice of medicine.

If you or the North Carolina Board of Medical Examiners have evidence of any violation of law, the names and details of such conduct should be reported to the North Carolina Board of Optometry forthwith so that we may proceed to exercise our legal responsibilities.

We are advised that the withholding of information of criminal or statutory misconduct might be deemed an obstruction of justice. If we do not hear otherwise, we shall assume that neither you nor your Board possess any evidence of statutory misconduct.

For the North Carolina State Board of Examiners in Optometry, I am

Sincerely,

John D. Robinson, O.D., Secretary
P. O. Drawer 609
Wallace, N.C. 28466
(919) 285-3160

cc: Board, Attorney

Item 3

NORTH CAROLINA STATE BOARD OF
EXAMINERS IN OPTOMETRY

October 4, 1985

Mr. Bryant B. Paris, Executive Secretary
North Carolina Board of Medical Examiners
222 North Person St., Suite 214
Raleigh, North Carolina 27601

Dear Mr. Paris:

Our investigation and inquiries have led to the discovery of no facts and the identity of no licensee of the North Carolina Board of Optometry relating to any statutory violation in the "post-operative care and following" of patients following cataract surgery as alluded to in your letter of September 5, 1985.

We have determined with particularity the scope of what optometrists do in their post-operative care and following of cataract surgery patients. The instructions for appropriate post-surgical care and following appear to be clearly understood between referring ophthalmologists and optometrists and appear to be assiduously adhered to by each professional so far as we can determine.

Please advise us specifically which steps or activities in the post-cataract surgery protocol are thought to be inappropriate. If we do not hear from you, we shall assume that neither you nor your Board have any real evidence or actual knowledge of any such specific alleged wrongful activities. On the other hand, if we are convinced that the scope of activity of any of our licensees you call to our attention is in excess of that proscribed by the General Statutues of North Carolina, we shall take the appropriate and necessary steps to terminate the activity and shall further report to you the identity of any ophthalmologist found to be aiding and abetting the violation of our laws.

For the North Carolina State Board of Examiners in Optometry, I am

Sincerely,

John D. Robinson, O.D., Secretary
P. O. Drawer 609
Wallace, N.C. 28466
(919) 285-3160

cc: Board, Attorney
Special Counsel

Item 4

Appendix 7

NORTH CAROLINA STATE BOARD OF
EXAMINERS IN OPTOMETRY

October 10, 1985

To: All licensees

From: The Board

Re: Post-operative care by optometrists

Enclosed are copies of three letters relative to the issue of post-operative care and/or following of patients by optometrists of which the Board feels you should be aware. The letter dated September 5, 1985, sets forth the views of the Board of Medical Examiners and is intended to publicize their views to the physicians of North Carolina. On receipt of a copy of this letter, the members of this Board met at length with its attorneys to review and research the legal issues and the allegations of statutory misconduct alluded to by the Board of Medical Examiners. The Board's letter dated September 19, 1985, to the Executive Secretary of the Board of Medical Examiners resulted from this meeting and is self-explanatory.

In the meantime, we have conducted investigations and inquiries pursuant to our statutory responsibilities to determine what, if any, steps or activities by licensees of this Board in post-operative care and/or following might be deemed to be inappropriate. The enclosed letter dated October 4, 1985, to Mr. Paris sets forth the findings of this Board based on the above referenced investigation and inquiries.

The purpose of this communication is to familiarize every licensee with the issues raised by the post-operative care and following of patients by optometrists over the last several years as the practice of optometry has evolved since the enactment of the "therapeutic drug law" in 1977. At the same time, we would remind each of you that like all of the members of the healing arts professions, you have ongoing moral, ethical, and legal responsibilities to refer those patients who you have determined are in need of the special skills or competencies of other practitioners, including ophthalmologists, when it is in the best interest of the patient to do so. A mutual respect for each practitioner's special skills and competencies is paramount in good patient care and should be established at the time of referral. Further, professional ethics demand that each practitioner's participation in patient care addresses the ultimate welfare of the individual being treated.

Finally, we would call your attention to the Optometry Laws of North Carolina Including Rules and Regulations of North Carolina Board of Examiners in Optometry, and most particularly G.S. 90-114, G.S. 90-118, and section .0100 of subchapter 42E of the NCAC which set forth the definition of the practice of optometry, the requirements for prescription and use of pharmaceutical agents, and professional responsibilities.

If there are questions, please feel free to contact the Board.

Item 5

N.C. BOARD OF EXAMINERS
RECEIVED
AUG 21 1986

State of North Carolina
Department of Justice
P.O. BOX 629
RALEIGH
27602-0629

LACY H. THORNBURG
ATTORNEY GENERAL

6 August 1986

SUBJECT: Optometrists; Post-operative care of cataract surgery patients; practice of medicine

REQUESTED BY: Bryant D. Paris, Jr. Executive Director
Board of Medical Examiners

QUESTION: Does post-operative care of cataract surgery patients by a licensed optometrist constitute the unauthorized practice of medicine?

CONCLUSION: The procedures identified herein as components of post-operative care of cataract surgery patients fall within the definition of optometry when done by a licensed optometrist and do not constitute the unauthorized practice of medicine.

The quesiton presented is whether post-operative care of cataract surgery patients by a licensed optometrist constitutes the unauthorized practice of medicine. The question arises from Medicare regulations and policies regarding optometric services of aphakia. The regulations and policies allow for surgical follow-up by optometrists provided that the services performed are within the scope of practice of optometry as determined by state law. Related questions concerning ethical considerations of referral and fee-splitting between opthalmologists and optometrists were not asked by the Board of Medical Examiners and are not addressed in this opinion

Aphakia is defined for purposes of Medicare as the absence of the natural crystalline lens of the eye whether or not an intraocular lens has been implanted. Opening and entry into the eye is performed by an opthalmologist who removes the cloudy natural lens, inserts the prosthesis (artificial lens) and then closes the entry wound. The opthalmologist examines the eye after surgery to determine whether the eye is healing without complications. If there are complications, the patient remains under the care of the opthalmologist. If there are no complications resulting from the surgery, the patient is ordinarily released from the care of the opthalmologist. If there are no complications, the question is whether and within what limitations an optometrist may provide post-operative care, such as determining the patient's unaided visual acuity, examining the eye and its adnexa (the surrounding structures), performing a slip lamp (biomicroscopic) examination of the external eye, performing a monocular opthalmoscopic and binocular indirect opthalmoscopic examination of the internal eye, determining the intraocular pressure by use of a tonometer, employing a phoropter (refractor) to determine whether corrective lenses are necessary for optimum vision, and if so, to prescribe the proper lens, and other ancillary procedures.

The Board of Medical Examiners submits that since surgery is excluded from the definition of optometry in G.S. 90-114, post-operative care is beyond the scope of practice of optometry because it is part of the surgery exclusion. The Board argues that post-operative care is a medical matter in that it involves a full range of complex medical judgments and is an essential part of the surgery process. The Board continues that the administration of intravenous fluids and medications and the removal of sutures is beyond the scope of practice of optometry. This Office agrees with the position of the Board of Medical Examiners concerning administration of intravenous fluids and medications and the removal of sutures and believes that the Board of Examiners in Optometry does not contest these matters. The Board of Medical Examiners also submits that prompt decisionmaking and use of medication during post-operative care does not permit collaboration by an optometrist with a medical doctor which is the prerequisite for prescribing medication, other than topical pharmaceutical agents, by an optometrist.

The Board of Examiners in Optometry takes the position that the practice of optometry as defined in G.S. 90-114 is a recognized exception under G.S. 90-18 to the unauthorized practice of medicine. The Board contends that pursuant to G.S. 90-114 an optometrist, within his or her area of specialized practice, may examine the human eye and its adnexa by any method; may diagnose, treat and refer for consultation or treatment any abnormal condition of the human eye and its adnexa; may employ instruments, devices, pharmaceutical agents and procedures when investigating, examining, treating, diagnosing or correcting visual defects or abnormal conditions of the human eye or its adnexa; and may prescribe and apply pharmaceutical agents and prosthetic devices to correct, relieve, or treat defects or abnormal conditions of the human eye or its adnexa. The Board contends that the scope of practice of optometry includes within it the procedures previously listed as components of post-operative care where there are no complications resulting from the surgery.

Surgery is a principal part of the practice of medicine under G.S. 90-18. Surgery is also specifically excluded from the definition of optometry under G.S. 90-114, which itself, when done by a licensed optometrist, is exempted from the unauthorized practice of medicine under G.S. 90-18. Therefore, provided there are no complications resulting from the surgery, if a procedure is included within the definition of optometry and not performed by means of surgery, the procedure, when done by a licensed optometrist, does not constitute the unauthorized practice of medicine but falls within the practice of optometry. Although the term "surgery" is not defined in G.S. 90-18, the breadth of the definition cannot prohibit the performance by an optometrist of those procedures reasonably included within the definition of optometry, under circumstances where there are no complications resulting from the surgery. The procedures identified as components of post-operative care fall within G.S. 90-114 in that they are done (i) to examine the human eye, (ii) to diagnose the condition of the eye, (iii) to refer the patient back to the opthalmologist for consultation or treatment (such as administration of intravenous fluids and medications and the removal of sutures), (iv) to investigate, examine, treat, diagnose or correct visual defects and abnormal conditions by the employment of instruments, devices, pharmaceutical agents and procedures, and (v) to prescribe and apply lenses. Furthermore, the procedures do not involve an invasion of the body so as to constitute surgery.

G.S. 90-114 provides that an optometrist may use and prescribe pharmaceutical agents upon collaboration with a medical doctor. The statute does not contain any exclusion for post-operative care.

The premise of the Board of Medical Examiner's argument is that post-operative care cannot be divorced from the surgical operation, which all agree falls within the practice of medicine. However, the structure of Chapter 90 of the General Statutes, entitled "Medicine, Allied Occupations", grants the entire field of health care to physicians licensed to practice medicine and then carves out specified areas for each of the allied occupations. It is the opinion of this Office that the procedures identified herein as components of post-operative care fall within the definition of optometry when performed by a licensed optometrist, and do not constitute the unauthorized practice of medicine where there are no complications as a result of the surgery.

LACY H. THORNBURG
Attorney General

Robert R. Reilly

Robert R. Reilly
Assistant Attorney General

Item 6

N.C. BOARD OF EXAMINERS
RECEIVED
1987
IN OPTOMETRY

BEFORE THE BOARD OF MEDICAL EXAMINERS
FOR THE STATE OF NORTH CAROLINA

IN RE: STEVEN MERLE WHITE, M.D.,
Respondent

CONSENT ORDER

This cause came to be heard before the Board of Medical Examiners of the State of North Carolina, at hearings held in the months of March, June, July and September, 1987. Evidence was presented concerning several charges and allegations against the Respondent. Petitioner was represented by James L. Blackburn and Respondent was represented by G. Eugene Boyce. The Notice of Charges and Allegations is attached to this Order and incorporated as if set out herein. Prior to conclusion of evidence, the parties have entered into a Stipulation consisting of the following findings of fact:

1. In the treatment of certain patients whose charts are identified in the Notice of Charges and Allegations, Steven Merle White, M.D., hereinafter "White," failed to perform an adequate preoperative examination or physical, in that he delegated to optometrists, nurses, or anesthesiologists the responsibility of performing these functions, prior to cataract surgery. The parties agree that it is not consistent with the standards of acceptable and prevailing medical practices in North Carolina for the surgeon to see a patient for the first time at the time of surgery without having performed a preoperative physical or obtained a preoperative history. White agrees that he will thoroughly examine each patient on whom he performs surgery, prior to surgery, and will review the patient's history with that patient. White further agrees that he will make an independent diagnosis of cataracts in each patient on whom he performs cataract surgery, and will not rely on others to make that diagnosis. White further agrees that he will have a detailed discussion with each patient regarding the diagnosis and the nature of the surgery, advising the patient fully of the risks involved.

2. White did not perform the 24-hour postoperative exam following cataract surgery on certain patients whose charts are identified in the Notice of Charges and Allegations. Instead, he delegated such examination to non-physicians, including nurses, and optometrists. The parties agree that delegation of the 24-hour postoperative exam following cataract surgery to non-physicians is not consistent with the standards of acceptable and prevailing medical practices in North Carolina. White agrees that he will perform each 24-hour postoperative exam on every patient on whom he performs surgery, with clear documentation that he has performed such examination, except in the case of emergency, in which event, he will ensure that another ophthalmologist performs such exam.

3. White did not examine many of the patients whose charts are identified in the Notice of Charges and Allegations at any time after he performed cataract surgery on that patient. This practice is not consistent with the standards of acceptable and prevailing medical practices in North Carolina. White agrees that he will provide postoperative care for each patient on whom he performs surgery until the healing process is complete. The parties agree that it is not improper to involve non-physicians in postoperative care, so long as the operating surgeon maintains full responsibility for the patient's postoperative care and examines the patient in the period following surgery to assess the healing process and the long-term results.

4. Appropriately detailed surgical notes describing each patient, his or her condition, the procedures, methods, prostheses, results, prognosis, and medication relative to the surgery, is in the best interests of the patient and should be prepared by or under the direct and immediate supervision of the surgeon. Even in the case of repetitive surgical procedures, a record should be kept of those routine details as well as all significant variations. Some of White's records gave the appearance of being incomplete or unduly duplicative. White has modified his record keeping procedures and methods and will henceforth continue to personally prepare separate, detailed surgical notes for each patient on whom he performs surgery.

5. White permitted non-physicians to sever sutures on some of those patients whose charts are identified in the Notice of Charges and Allegations. The decision to sever a suture and the act of severing a suture are medical acts. Therefore, the decision to sever a suture should be made by the operating surgeon, and the act of severing a suture must be performed only by the operating surgeon or by those health care practitioners to whom this act may be legally delegated.

6. On several occasions, in the treatment of some patients whose charts are listed in the Notice of Charges and Allegations, White allowed non-physicians to sign the prescriptions for medications. It is improper to permit non-physicians to prescribe medicine, except as provided by certain North Carolina General Statutes; one of which is Section 90-114, which permits optometrists to prescribe medicine if there is communication and collaboration with a licensed physician. The Board is of the opinion that communication and collaboration as described in North Carolina General Statutes Section 90-114 requires consultation between the ophthalmologist and optometrist regarding the specific patient for whom the medication is prescribed. In addition, the optometrist should consult with the ophthalmologist on each occasion on which medicine is prescribed. White agrees that he will not permit non-physicians to prescribe medicine except as permitted by Statute, and that in those situations described by North Carolina General Statutes Section 90-114, he will consult with the optometrist specifically with regard to the patient for whom medication is to be prescribed.

In consideration of the above finding of facts:

1. The Board of Medical Examiners hereby strongly reprimands Steven M. White, M.D. with respect to each of the following charges contained in the Notice of Charges and Allegations: 2(a), 2(b), 2(c), 2(d), 2(e), the portion of 2(h) concerning removal of sutures, 3(a), 3(b), 3(c), 3(d), 3(e), 5(a), and the portion of 5(b) concerning removal of sutures;

2. The Board of Medical Examiners hereby dismisses each of the following charges contained in the Notice of Charges and Allegations: 1, 2(f), 2(g), all of 2(h) except the portion concerning removal of sutures, 2(i), 3(f), 3(g), 4, all of 5(b) except the portion concerning removal of sutures;

3. The Board of Medical Examiners will continue to monitor White's practice to see that he complies with the requirements of this Order;

4. White agrees that he will open his records to agents of the Board at any reasonable time for inspection to assess compliance with the requirements of this Order;

5. White will obey all laws;

6. Failure of White to comply with this Order shall be grounds, after notice and a hearing, for review, including revocation or suspension of his license to practice medicine.

By order of the Board of Medical Examiners of the State of North Carolina, this the _____ day of ___________, 1987.

BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NORTH CAROLINA

BY: ______________________________

STEVEN M. WHITE, M.D.

Steven M White

CONSENTED TO:

PETITIONER, BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NORTH CAROLINA

BY: James L Blackburn
James L. Blackburn,
Attorney for Petitioner

RESPONDENT, STEVEN M. WHITE, M.D.

BY: G Eugene Boyce
G. Eugene Boyce,
Attorney for Respondent

Item 7

NORTH CAROLINA STATE BOARD OF
EXAMINERS IN OPTOMETRY

March 16, 1988

To: N. C. licensed optometrists and others who may be concerned in the post-operative care and following of cataract surgery patients

From: John D. Robinson, O.D., Secretary

Re: Sequence of events leading to the October 1987 Consent Order in the matter of N. C. State Board of Medical Examiners v. Steven Merle White, M.D. and the reaffirmation by the N. C. State Board of Examiners in Optometry of the statutory authority of licensed optometrists to participate in the post-operative care and following of cataract surgery patients

This Board is being frequently asked to comment as to the legal status of optometrists participating in post-operative care following cataract surgery and the implanting of an intraocular lens. In order to respond to requests for an accurate accounting of events that led up to the above referenced Consent Order and the manner in which some have misinterpreted the terms of the Order, the Board and its legal counsel has prepared the following sequence of events, including the entering of the Consent Order, its application to the lawful scope of practice of optometrists in North Carolina, and the standard of care acceptable in optometry and ophthalmology.

The issue of participation of optometrists in the provision of post-operative cataract services (routine follow-up visits) was raised in the summer of 1984. The appropriateness and the manner in which optometrists who were participating in post-operative care was reviewed early on by the fiduciary agent, Prudential/Medicare. After all requested information was supplied to HCFA and the regional office, a memorandum dated September 20, 1984 was furnished to business managers of a number of ophthalmological practices wherein Virgil Tuttle, Associate Manager, Medicare Claims Division, states that "the surgical fees for cataract surgeries have traditionally included components for follow-up services, management and/or complications." He went on to say that "the regional office advised that providing some of the follow-up visits under arrangements with optometrists who bill you for these services continues to meet the traditional definition of a global surgical fee." Ophthalmologists who were returning patients to optometrists for post-operative care services were requested to provide Prudential with a list of those providers that were providing these services so that they could be identified and claims for duplicate services denied since Medicare would not be liable for claims from optometrists who were being reimbursed by the operating surgeon as part of his global surgical fee.

Although this system was not illegal, it did on its face appear susceptible of abuse.

In December 1984, Prudential issued a Medicare Bulletin relative to "KICKBACKS, REBATES" stating that it had been reported that some optometrists may have referred patients for a flat fee or an opportunity to provide post-operative follow-up care, the result of which may result in increased cost to the Medicare program. The Bulletin went on to say "depending on the nature of the offer and the nature of the encouragement, these or similar arrangements may be in violation of a criminal statute, Section 1877(b) of the Social Security Act." In the best interests of all parties, a change in the system was deemed advisable.

During the period between September 1984 and September 1985, there was considerable activity on the part of a number of ophthalmologists, including a number of letters that were sent to the officials of Prudential, HCFA, members of Congress, the Attorney General of North Carolina, and numerous other state and federal agencies. Additionally, there were a number of Resolutions on the part of local societies of ophthalmology, the N. C. Society of Ophthalmology, and the Eye Care Committee of the N. C. Medical Society. Among the most vocal of the ophthalmologists, as witnessed by letters over his signature and by references within the newsletters and minutes of the N. C. Society of Ophthalmology and/or the Eye Care Committee of the N. C. Medical Society, was Scott Bowers, M.D. of Wilson, N.C.

On September 5, 1985, Bryant D. Paris, Jr., Executive Secretary of the N. C. Board of Medical Examiners, wrote to Eugene A. Stead, Jr., M.D., editor of the N. C. Medical Society Journal, requesting that he publish the "views of the Board in the next issue of the Journal". It was the view of the Board that the providing of "post-operative care and following" by optometrists "constitutes the practice of medicine" and that "the practice of permitting persons who are not licensed to practice medicine in the State of North Carolina to provide such care is specifically disapproved by the Board".

On September 19th, the Board of Examiners in Optometry wrote to Mr. Paris requesting that if the Board of Medical Examiners had "evidence of any violation of law" insofar as the practice of optometry was concerned, particularly as such practice involved post-operative care and following of patients who had been referred for surgery, then "the names and details of such conduct should be reported to the North Carolina Board of Optometry forthwith so that we may proceed to exercise our legal responsibility".

During the period between September 19 and October 4, 1985, the Board of Examiners in Optometry conducted a survey among ophthalmologists who were thought to be offering patients whose surgery was routine and without complication an opportunity for co-management by referring them back to optometrists whom they had determined to be competent to monitor the patient and to provide post-operative care and following, upon the patient's request.

On October 4, 1985, the Board again wrote to Mr. Paris wherein he was informed that the Board's investigations and inquiries "have led to the discovery of no facts and the identity of no licensee of the North Carolina Board of Optometry relating to any statutory violation in the 'post-operative care and following' of patients following cataract surgery". This Board went on to request that the Board of Medical Examiners advise "specifically which steps or activities in the post cataract surgery protocol are thought to be inappropriate". The Board of Medical Examiners has never to this date replied to either of these letters.

On October 10, 1985, this Board wrote to every licensed optometrist and included in the mailing a copy of the "view" of the Board of Medical Examiners concerning post-operative care and our two letters to the Board of Medical Examiners referred to above. Every licensee was reminded that "like all members of the healing arts professions, each has ongoing moral, ethical, and legal responsibilities to refer those patients who are determined to be in need of the special skills and competence of other practitioners, including ophthalmologists, when it is in the best interest of the patient to do so".

On January 13, 1986, Prudential/Medicare mailed a notice to every licensed optometrist and to those ophthalmologists known to be referring patients back to optometrists for post-operative care. They advised that "effective immediately, procedure code W9245** has been assigned for routine follow-up cataract surgery care provided by an optometrist or physician other than the operating surgeon. The operating surgeon will use modifier 54 with the appropriate surgical procedure code." It was further stated that "Medicare benefits for the follow-up care will be based on a global allowance, and will be subject to coinsurance and deductible. The surgical allowance will be reduced accordingly. Non-routine follow-up care by the operating surgeon due to complications, etc., will still be considered as part of the global surgery allowable."

In late January of 1986, the North Carolina Board of Medical Examiners subpoenaed 133 charts from the White Ophthalmology Clinic.

On May 7, 1986, Dr. Steven M. White was served with a Notice of Charges and that a hearing would be held on the charges by the Board of Medical Examiners.

On May 29, 1986, the N. C. Board of Medical Examiners made a formal request to the Attorney General of North Carolina for an opinion on post-operative care pursuant to their earlier published "view".

In June of 1986, this Board was informed of the request of the Board of Medical Examiners for an opinion and was given an opportunity to submit comments or arguments on behalf of this Board in the matter to be considered. This Board forwarded to the Attorney General a statement of its conclusions in early July.

On July 7, 1986, counsel for Steven M. White, M.D. wrote to the N. C. Board of Medical Examiners as follows: "I have formed the studied opinion that the Board of Medical Examiners of the State of North Carolina is being 'used' to its detriment and has been persuaded to act not in the public interest. This prosecution was undoubtedly precipitated by the comment made by Medicare officials to Dr. Scott Bowers that they would continue their current reimbursement procedures directly to optometrists until both State and Federal laws were amended or until a State Board took 'licensure revocation action.'"

On August 7, 1986 the Attorney General rendered his final opinion wherein it was concluded that the procedures identified as components of post-operative care of cataract surgery patients "fall within the definition of optometry when done by a licensed optometrist and do not constitute the unauthorized practice of medicine". This conclusion, which constitutes the opinion of the State's Attorney, was a direct answer to the question from the Board of Medical Examiners "does post-operative care of cataract surgery patients by a licensed optometrist constitute the unauthorized practice of medicine?"

From August 1986 until December 1986, upon motion of Mr. Boyce, the Board of Medical Examiners was restrained by the Court from proceeding in the White case. On March 6, 1987, the hearing of the charges against Steven Merle White, M.D. commenced before the Board of Medical Examiners of the State of North Carolina in Greenville, North Carolina.

In April of 1987, in its transmittal document number 1182, the Health Care Financing Administration forwarded to its fiduciary agents a revision of Part 3 of the Carriers Manual which revised and/or replaced pages 2-18.9 - 2-18.10. The change in policy being effective April 1, 1987. "Section 2020.25. Optometrists.--This section is being revised to implement section 9336 of the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509). Section 9336 provides that effective April 1, 1987, a doctor of optometry is considered a physician for Medicare purposes with respect to the provision of any item or service the optometrist is authorized to perform by State law or regulation."

On Sunday, July 19, 1987, at the continuation of the hearing of Steven M. White, M.D., the transcript of the hearing as found in Volume 8 on pages 114 - 117 records a series of questions, answers, and statements in an exchange between Dr. Duckett, president of the Board and presiding officer at the hearing, and Dr. White concerning Dr. White's billing practice in those instances where he had performed surgery and that the patient had been followed by a referring optometrist. On Page 116 of the transcript, Dr. Duckett makes a statement followed by a question. In making the statement, Dr. Duckett looked to his left and to his right in what appeared to be an attempt to ascertain if any of his fellow Board members disagreed or objected to what he was saying. Neither the attorney for the Board, nor any member of the Board of Medical Examiners, made any statement or appeared to be disturbed by the statement Dr. Duckett made prior to his question. This statement as found on page 116 of the transcript is as follows. "If one of the cases is referred, and let's say the patient calls -- in other words you have signed the Medicare form and you have referred some of the postoperative follow-up to the optometrist, which we all know is legal. I don't think that is a question in our mind whether or not it is legal." He then went on to ask the question, "that patient might call you back in some instances about a problem, is that correct?" The answer was "yes". Dr. White was then asked, "the optometrist might call you and send the patient back?" The answer again was "yes". He was then asked, "because there is a problem?" The answer was "yes". He was then asked, "when the patient comes back, do you then have to resubmit a bill for that part of your care?" Dr. White's answer was, "no, I post no fees for anything -- for a four-month period, anything that pertains to cataract surgery". A copy of page 116 is attached.

On September 13, 1987, the Board of Medical Examiners and Steven Merle White, M.D., along with both counsel, negotiated and agreed upon a Consent Order which when signed and entered would conclude the matter between Dr. White and the Board. This Consent Order was agreed to prior to any affirmative evidence having been presented by Dr. White in his defense and even before he had ever been questioned by Mr. Boyce.

The agreed upon Consent Order contained a number of stipulations consisting of six numbered paragraphs of "Findings of Fact". Those Findings of Fact contained in this Consent Order that had bearing on the post-operative care and following of cataract surgery patients by optometrists are contained in numbered paragraphs two and three.

In paragraph two, it is stated that Dr. White did not perform the twenty-four hour post-operative examination following surgery on certain patients whose charts were identified in the notice of charges and allegations and that he had, on certain occasions, delegated such examinations to others, including nurses and optometrists. (These occasions occured between February 1985 and May 1985 following the sudden termination of one of the M.D.s in the White Clinic.)

From the beginning, the parties were not in disagreement as to most all of the acceptable standards of practice. The parties agreed that the twenty-four hour post-operative exam following cataract surgery should be done by the operating surgeon and that the operating surgeon, in this instance Dr. White, will perform the twenty-four hour post-operative exam on every patient on whom he performed surgery, with clear documentation that he has performed such examination. The parties further agreed that in the case of an emergency if the operating surgeon, in this instance Dr. White, was unable to perform the twenty-four hour post-operative examination, he will insure that another ophthalmologist perform such an examination.

In paragraph three, it is stated that Dr. White did not examine certain patients whose charts were identified in the notice of charges and allegations at any time after he performed surgery on the patient (this is a continuation of the findings stated in paragraph two above). The parties agreed that the better and acceptable minimum practice is for the surgeon to see the patient at the 24 hour examination and then again at the 3 or 4 month post-operative examination to make a final long-term assessment of the patient's eye. Further, Dr. White agrees that he will provide post-operative care for each patient on whom he performed surgery until the healing process is complete. HOWEVER, the parties - Steven M. White, M.D. and the North Carolina Board of Medical Examiners - agree that "it is not improper to involve non-physicians in post-operative care so long as the operating surgeon maintains full responsibility for the patient's post-operative care and examines the patient in the period following surgery to assess the healing process and the long-term results."

Herein lies the key finding by the Board of Medical Examiners as to the appropriateness of optometrists (or as expressed in the Consent Order, "non-physicians") participating in the post-operative care and following of cataract surgery patients, their earlier "view" as expressed on September 5, 1985 notwithstanding. The statutes of the State of North Carolina which govern disciplinary hearings before licensing agencies are both detailed and implicit in that consent orders entered into by the agency and the respondent, in this case the Board of Medical Examiners and Steven M. White, M.D., are binding on both parties and constitute the law of the case. Since the Board of Medical Examiners is bound by the Order entered in the matter of Steven M. White, M.D., their "view" as expressed in September of 1985 was premature and not binding since the accepted standard of care for post-operative care in cataract surgery had not been properly established at that time. This recognition of continuing responsibility in co-management has always been the standard as exemplified by the very elaborate communication procedures and reporting protocols during the post-operative period.

It has never been the position of the Board of Optometry that in the co-management of cataract surgery patients, the operating surgeon should give up the responsibility of determining the appropriate time that his surgical patient should be returned to the referring practitioner for following. This is a judgment that, of necessity, must be made on a case by case basis by individual practitioners.

In other words, the parties had no dispute in the final analysis of what is the accepted standard of care for post-operative care in cataract surgery in North Carolina.

Inquiries concerning this memorandum may be addressed to the Secretary of the Board at:

321 E. Main St.
PO Drawer 609
Wallace, NC 28466
(919) 285-3160 or 1-800-426-4457

cc: Board, Attorney
Special Counsel

Item 8

Appendix 11

N. P[illegible] DAVIS, ~~II, M.D.~~ F.A.C.S.
ROGER Z. THURMAN, M.D., F.A.C.S.

OBSTETRICS - GYNECOLOGY
INFERTILITY - ENDOCRINOLOGY
JAMES B. GLOVER, M.D., F.A.C.O.G.
JOHN A. KIRKLAND, M.D., F.A.C.O.G.
HUITT E. MATTOX, M.D., F.A.C.O.G.
ROBERT L. TOMLINSON, JR., M.D., F.A.C.O.G.
DANIEL P. MICHALAK, M.D.

PEDIATRICS
EDWARD Y. C. THORNE, M.D.
EARL E. FISHER, M.D.
JAMES R. BUSCH, M.D., F.A.A.P.

GASTROENTEROLOGY
JERRY C. WOODARD, M.D., F.A.C.P.

UROLOGY
THOMAS L. GRIFFIN, M.D., F.A.C.S.

CARDIOLOGY
J. ALLEN WHITAKER, M.D., F.A.C.P., F.A.C.C.

NEUROLOGY
HAROLD A. LADWIG, M.D.

EXECUTIVE VICE-PRESIDENT
BENJAMIN BROCKWELL

[illegible] OSWALD, M.D.

INTERNAL MEDICINE - CARDIOLOGY
WILLIAM B. YOUNG, M.D.
JOHN J. LUND, M.D., A.F.A.C.C.

INTERNAL MEDICINE - NEPHROLOGY
JOSEPH D. RUSSELL, M.D.
ROGER W. LAMANNA, M.D.

INTERNAL MEDICINE - PULMONOLOGY
LINDSEY E. de GUEHERY, M.D.

INTERNAL MEDICINE - RHEUMATOLOGY
LAWRENCE D. KRABILL, M.D.

HEMATOLOGY - ONCOLOGY
DUDLEY B. ANDERSON, M.D., F.A.C.P.

ORTHOPAEDICS
A. TYSON JENNETTE, M.D.
ROBERT A. APPERT, M.D.

OPHTHALMOLOGY
SCOTT P. BOWERS, M.D.

[illegible] BURBA, M.D.

FAMILY PRACTICE
A. R. BURBA, M.D.
MICHAEL BOWEN, M.D. - STANTONSBURG
MICHAEL SUNDERMAN, M.D. - STANTONSBURG
RICHARD K. TORREY, M.D. - MIDDLESEX

FAMILY PRACTICE - AFFILIATE
I. EDWIN DREW, M.D. - MACCLESFIELD

OTOLARYNGOLOGY
BRONCHO-ESOPHAGOLOGY
SPEECH AND HEARING CLINIC
L. ASHBY ADAMS, M.D.
CARYL GRAHAM, M.S., C.C.C.A.

RADIOLOGY
FRANKLIN J. YOUNGS, M.D.
D. REID TICKLE, M.D.
E. FRANK COLLINSON, M.D.
GEORGE W. EASON, M.D.

PSYCHOLOGY
GARY H. BACHARA, Ph.D.

PHYSICAL THERAPY
PAULA MICHALAK, L.P.T.

CAROLINA CLINIC, INC.
1700 S. TARBORO STREET
WILSON, NORTH CAROLINA 27893
PHONE 291-1300

N.C. BOARD OF EXAMINERS
RECEIVED
SEP 17 1987
IN OPTOMETRY

August 27, 1987

Senator John Shoemaker
C/O Senate Consumer Protection &
Professional Licensure Committee
Senate Office Bldg.
Harrisburg, PA 17101

Dear Senator Shoemaker:

During the public hearing on Senate Bill 657 (therapeutic drug use for optometry), questions were asked regarding the malpractice situation of high volume surgeons in my home state of North Carolina. While I did not broach this subject during my prepared remarks, I do feel it is certainly a valid subject of inquiry for the Committee. Obviously, I was ill prepared to give facts and figures regarding malpractice statistics in North Carolina. Medical malpractice is a very touchy subject with physicians these days, and Medical Mutual of North Carolina (the main professional liability insurance carrier for the State of North Carolina) is very reluctant to give specific information regarding any one particular physician's malpractice profile to any other physician or outside party. The reason for this is obvious - they can be sued if they release specific information regarding patients or physicians without proper authorization. Nevertheless, I agree with you that some type of generic tabulation of these statistics should be obtainable and made available to both the public and the appropriate legislative committees. I have never really tried to obtain this sort of statistical information before, but I will certainly give it my best shot. As soon as I can obtain any information on this subject which I think might be of assistance to you, I will be forwarding it to your offices immediately.

I would also like to explain very briefly my hesitation and inability to answer the question regarding the rate of occurrence of malpractice by high volume surgeons in a direct and forceful manner. While I have no access at this time to any sort of generalized tabulated statistics revealing the rate of occurrence of malpractice in high volume practices, I do have rather intimate knowledge of certain high volume surgeons in this state who have had repeated difficulties with medical malpractice. Some of these cases (with which I am intimately familiar) involve patients who were optometrically scheduled for surgical procedures and were followed postoperatively during their critical recovery period by optometrists - again, after receiving the surgery at high volume surgery centers. Some of these patients feel that optometrists participating in the preoperative and postoperative management of their surgical care subjected them to a lower level of care and expertise than would have been otherwise available had their operating surgeon provided such care to them. These patients feel they have been damaged and are pressing their claims in the various State and Federal courts. I have performed medical chart review work in some of these cases as an expert medical witness, and I must frankly agree with many of the patients that their problems were avoidable had their operating surgeon bothered to provide preoperative or postoperative care for them. I have done chart reviews for legal firms regarding medical malpractice cases and will undoubtedly do others in the future. In addition, I have reviewed over 130 medical records for the North Carolina Board of Medical Examiners - most generated by high volume cataract practices. As such, I am not free to comment about specific patients, surgeons, procedures, dates, or other information which might jeopardize ongoing litigation or investigations by the Board of Medicine. Although I have much specific information regarding the malpractice situation of certain of these individuals, I am simply not free to share this specific information with anyone at this time. Hence, when specific facts and figures were requested regarding this issue, I was simply not prepared (or legally permitted) to release some of the information I possess. Quite frankly, it is frustrating to have direct knowledge about such a subject and not be about to use it in a public hearing.

I do have knowledge of a high volume cataract surgeon in North Carolina who has had difficulties involving multiple medical malpractice cases (at least five) over the last year or so. I believe I alluded to this in my testimony but was unable to give any further specific information. Until these cases are settled or adjudicated and become a matter of public record, I will be unable to provide any specific information to your Committee about them. I will try, however, to obtain from the appropriate professional liability insurance carriers valid and verifiable statistics regarding the rate of medical malpractice among high volume surgeons - if such information has been tabulated and I can get them to release it to us.

I did want to write and let you know that the obvious evasiveness with which I eluded the Committee's questions on this subject was based on my desire to not jeopardize or impugn any ongoing investigation or litigation involving those malpractice cases of which I have knowledge. That aside, I will make every best effort to locate the information you have requested and forward it to you as soon as possible.

It was a distinct honor and privilege to visit the Great State of Pennsylvania and address the Senate Consumer Protection and Professional Licensure Committee. Again, thank you for the opportunity to address the Committee.

Sincerely yours,

Scott P. Bowers, M.D.

SPB/tp

Item 9

Prudential-Medicare, High Point, North Carolina

Billings for cataract surgery to Medicare for calendar years 1985 and 1986

YEAR	PROCEDURE CODE	PROCEUDRE	# OF SURGIES	# OF BENEF
1985*	66983	Intracap Cat Ext	17,459	14,700
	66984	Extracap Cat w IOL	6,865	6,200
Total 1985			24,324	20,950
1986	66983	Intracap Cat Ext	1,753	1,562
	66984	Extracap Cat w IOL	23,630	19,000
Total 1986			25,385	20,562

* In 1984 ALL cataract extractions were billed under the same code, i.e. 66980, therefore, there could be some error in 1985 figures based upon coding error.

Billings for post-operative follow-up care by optometrists

1985	W9245	Post-Op F/U	No Data Available	
1986	W9245	Post-Op F/U	2,628	2,312

APPENDIX 4.—CASE SUMMARIES DOCUMENTING FRAUDULENT AND/OR ABUSIVE PRACTICES BY OPHTHALMOLOGISTS PARTICIPATING IN THE MEDICARE PROGRAM

CODING SCHEME

CASES SUBMITTED FOR THE RECORD
BY DR. CHARLES WRIGHT

Field Hearing of the Senate Special Committee on Aging
"Kickbacks in Cataract Surgery"

May 23, 1988

Each of the following 50 case summaries submitted for the record was assigned a code by Committee staff to differentiate among cases that involve both ophthalmologists and optometrists from those that involve only one practitioner. The coding is simply intended as a guide to readers, and does not reflect the views of the Committee or staff on the nature of the case or its relevance to the immediate focus of the Committee hearing.

All cases were provided to the American Optometric Association (AOA) on May 27, 1988 for review and, at AOA's option, official comment as part of the final hearing record.

CODING

A - Involvement of both ophthalmologist(s) and optometrist(s).

B - Involvement of ophthalmologist(s) only.

C - Involvement of optometrist(s) only.

D - Insufficient documentation.

PREFACE

These case summaries were submitted by various ophthalmologists who now practice in the State of North Carolina. These cases were assembled to document various types of fraudulent and/or abusive practices by ophthalmologists participating in the Medicare program. Concerns have been raised that confidential medical information about patients might be revealed as a result of these efforts. Because of these concerns, the ophthalmologists of North Carolina have submitted these case summaries in generic form with identifying data deleted such that patients' confidentiality can be maintained. Therefore, these cases are being assembled and presented in a format similar to what one would find at a major medical conference. Even though specific names and places have been deleted, these cases represent real people and real occurrences. Medical records exist in the offices of ophthalmologists throughout North Carolina to verify and corroborate these case reports.

The search for this information was initiated on or about May 3, 1988. A hearing had been scheduled before the U.S Senate Special Committee on Aging in Philadelphia on May 23, 1988 concerning the subject of kickbacks in cataract surgery. Obviously, 20 days is an inadequate period of time to canvass all the ophthalmologists practicing in North Carolina. Roughly 10 to 15% of the ophthalmologists practicing in North Carolina (approximately 35 to 40 of 300) were contacted by telephone and were asked to submit cases from their geographic areas that they could document by either first hand experience or a valid medical record. Over the next ten days, cases were mailed in response to this appeal and these summaries constitute the material in this case book. It should be noted that no official organ of the State or Federal Government was involved in the collection of this information. The State and National Ophthalmic Societies have no subpoena power or information gathering authority and cannot compel ophthalmologists to provide this kind of information. These cases were assembled on very short notice in a purely voluntary effort. Many ophthalmologists were (and are) reluctant to cooperate with this effort for a variety of reasons:

1) They worry that confidential patient data will be revealed jeopardizing patients' anonymity.
2) Physicians who criticise other physicians are often the victims of lawsuits alleging libel or slander. Doctors are often afraid to report misconduct by other doctors. This is not a "conspiracy of silence" - it is an atmosphere of fear.
3) Most physicians do not keep lists of patients who have been misled or abused. Simply locating this information is often an extremely cumbersome task.
4) Many patients have filed grievances or suits against doctors accused of fraudulent or abusive practices and are either in the midst of ongoing litigation or have accepted an out of court settlement. Most out of court settlements stipulate that the patient must not discuss the details of his or her case with any outside parties lest the settlement be forfeited and/or countersuits be instituted. Many patients are afraid to talk about their unfortunate experiences with surgeons who have taken advantage of them and are unwilling to share these experiences with even their family physician.
5) Physicians fear that good faith reporting of a colleague's wrongdoing will result in a loss of respect or acceptance by their peers.
6) Many physicians feel that contributing any information regarding fraudulent or abusive practices by their colleagues will directly or indirectly reflect back on their profession as a whole and ultimately be used to justify punitive actions against the entire profession. This fear has not been wholy unfounded as evidenced by similar congressional hearings conducted in recent years.
7) Lastly, many physicians feel that any attempt to document abusive practices by other physicians is simply a waste of time. These doctors feel that Congress and the Administration have shown no real interest in quality of care issues and are only looking for justification to cut reimbursement levels for physicians in general (and ophthalmologists in particular) across the board.

A poll was taken by the North Carolina Society of Ophthalmology in 1986 to determine the standard of care for cataract surgery patients. The results conclusively showed that the vast majority (greater than 98%) of the ophthalmologists in North Carolina provided adequate preoperative and hands-on postoperative examinations throughout the entire postoperative recovery period for all of their patients. An extremely small percentage of physicians were identified who did not adhere to basic minimum standards of care. The ophthalmologists of North Carolina would like to point out to the Senators on the Committee that the cases represented in this compilation are not representative of the average ophthalmologist in North Carolina. These abuses are characteristic of only a very small percentage of the ophthalmologists practicing now in North Carolina. Unfortunately, these doctors affect huge numbers of patients and represent enormous expenditures of both public and private health care funds.

Respectfully submitted,

Scott P. Bowers, M.D.

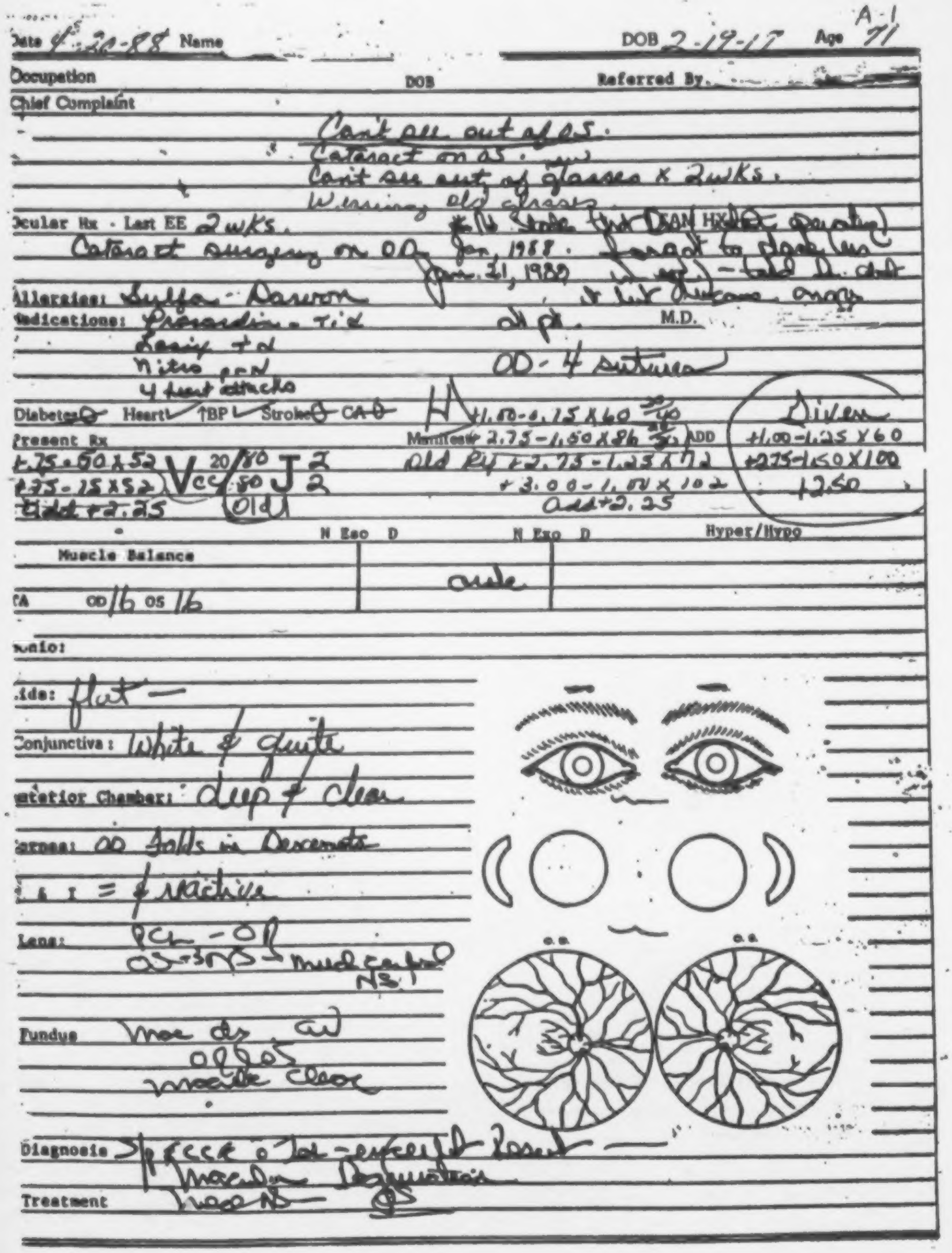
Walter Wright, M.D.

SPB/tp

CASE REPORTS

Submitted by Ophthalmologists from North Carolina

CASE 1:



A-1

Date 4-20-88 Name

DOB 2-19-17 Age 71

Occupation

DOB

Referred By

Chief Complaint

Can't see out of OS.
Cataract on OS.
Can't see out of glasses x 2wks.
Wearing old glasses.

Ocular Hx - Last EE 2wks.
Cataract surgery on OD Jan, 1988.
Jan. 21, 1988
[illegible] Stroke [illegible] (DEAN HX [illegible] operation) forgot to [illegible] [illegible] - told Dr. [illegible] [illegible] [illegible] op pt.

Allergies: Sulfa - Darvon

Medications: Procardia - t.i.d
Lasix q.d
Nitro p.r.n
4 heart attacks

M.D.

OD - 4 sutures

Diabetes ⊖ Heart ✓ ↑BP ✓ Stroke ⊖ CA ⊖

H +1.50-0.75 X 60 20/40

Manifest +2.75-1.50 X 86 20/25 ADD

Present Rx
+.75-.50 X 52
+.75-.75 X 52
Add +2.25

Vcc 20/80 J 2
20/80 J 2
(Old)

Old Rx +2.75-1.25 X 72
+3.00-1.00 X 102
add +2.25

Given
+1.00-1.25 X 60
+2.75-1.50 X 100
+2.50

Muscle Balance

N Eso D

N Exo D

Hyper/Hypo

ortho

TA OD 16 OS 16

Gonio:

Lids: flat —

Conjunctiva: White & quiet

Anterior Chamber: deep & clear

Cornea: OD folds in Descemets

& I = & reactive

Lens: PCL - OD
OS 3+NS - mod central NS

O.D.

O.S.

Fundus mac dz OU
c/d .2 OS
macula clear

Diagnosis S/p ECCE c IOL - excellent Result —
Macular Degeneration

Treatment [illegible] — OS

CASE 2:

Date 4-29-88 Name DOB 10-31-14 Age 73

Occupation DOB Referred By: Dr.

Chief Complaint 2nd opinion

Cataract on OS. for [illegible] purpo

Ocular Hx - Last EE 4-25-88 c̄ Dr. FAM HX: cousin glaucoma

OD ECCE c̄ IOL 1986 uncle diabetic

Allergies: Ampicillin, Macrodantin, Septra

Medications: Donnatal M.D.

Gall Bladder surgery 1982, Poly - 1985 Prostate 1979

Diabetes ⊖ Heart ⊖ ↑BP ⊖ Stroke ⊖ CA ⊖ H) -1.00 -1.50 x 15.5 20/20 H) -1.25 -3.00 x 1 20/20

Present Rx Manifest ADD

+.75 -2.00 x 115 Vcc 20/30 J 1

+1.00 -2.50 x 15 Vcc 20/40 J 2

+2.25

N Eso D N Exo D Hyper/Hypo

Muscle Balance ortho

TA OD 16 OS 16

Gonio:

Lids: WNL

Conjunctiva: W.Q

Anterior Chamber: D.C

Cornea: C

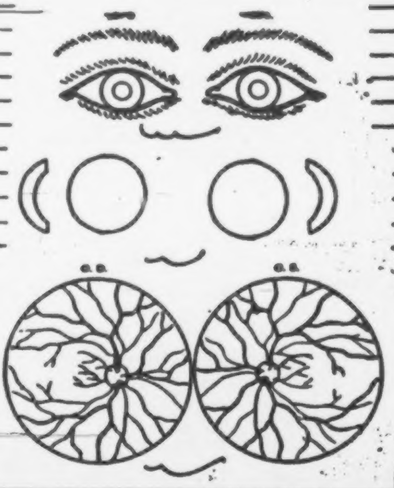
Iris: [illegible]

Lens: +2+3 NS

suggest PCL - OD

c̄ good opening

Fundus wnl



Diagnosis Cortical [illegible] OS, S/P ECCE PCL —

Treatment [illegible] [illegible] [illegible] [illegible] [illegible] 20/70 ! OS (over)

CONTINUATION

NAME

ADDRESS DATE

Patient had glare test, tells his cataract seemed not get better — [illegible] believes that his cataract slightly [illegible]. There are minimal changes of [illegible] of Rx — suggest NO Surgery —

Pt. arguing!

CASE 3:

Summary of Case of L. M.:

87 year old, widowed, white female who lives in , NC. Patient has daughter and son-in-law who live in , NC, in the western part of the state. Son-in-law is Dr. , who is a retired general surgeon.

Patient underwent a cataract extraction with intraocular implant in the left eye in 1985, in Waynesville, NC. This was done to be close to her family. She apparently did very well after this surgery, done by Dr. . She was then back in the area and followed by C. W. O.D., for routine eye care. She was found to have a cataract in the right eye in October or November, 1986. She was referred to the Eye Clinic in for evaluation. She underwent evaluation by a physician there and arrangements were made for surgery to be performed the week prior to Thanksgiving. It is unclear if this same person who examined her did the surgery on her, or not. She underwent cataract extraction the week prior to Thanksgiving, in November, 1986. During the operation, a phacoemulsification procedure, there was a posterior capsule rupture and nucleus was displaced posteriorly. The eye was sewn up. The patient's daughter, who was with her, was told of the complication. The surgeon adamantly recommended that the patient be taken to , that day. The patient's daughter asked for the name of another surgeon, in , who could be contacted. The daughter states that there was no option given as to the availability of care of other options for someone in the area. She then requested that the surgeon talk to her husband, the general surgeon in , NC. At that time, the family then decided to go to , where she was seen by another surgeon, at 6:00 PM, on the same day. The patient was taken to surgery at 6:00 AM the following day, where a vitrectomy with secondary intraocular implant was also performed at the same setting. The patient was then sent home on an outpatient basis, the same day as surgery. She was sent back to O.D. for her postoperative care. The family reports that during the postoperative course there were double billings for examinations by an optometrist, as well as by the operating surgeon. There is also a question of double billing for the intraocular lens.

Points to consider in this case:

1. Patient's son-in-law is a retired general surgeon who has considered bringing suit against this group.
2. Patient's son-in-law is willing to testify.
3. Lack of openness about available eye care in the area for postoperative complication.
4. Outpatient treatment and immediate transfer back to referring ophthalmologist in a case of a severely inflamed and complicated case.
5. Possible double billing for postoperative care.
6. Possible double billing for implantation of implant.

Subsequently, the patient had developed this pseudophakic bullous keratopathy in the left eye. Her corneal transplant was performed in June, 1987. Fortunately, the patient has vision of 20/30 in the left eye. Her right eye remains with poor vision of 4/200 with diffuse vascular occlusive change of the macular area. This subsequently underwent laser photocoagulation without improvement of the vision, in the right eye. The retinal evaluation and laser photocoagulation was done by Dr. and the corneal transplant was done by

CONTINUATION

NAME

ADDRESS

DATE

Summary - (See Initial Complaint)
[illegible] glasses
+1.00-1.25x60 — 20/30+
+2.75-150x100 — 20/30

Patient had cataract extraction of OS [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] OS [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] OS.

[illegible] [illegible] gl. has [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] OS [illegible] [illegible] [illegible]. [illegible] [illegible]

5-2-88 Re ✓ gl.

no gtts.

V 20/60
cc 60

Can't wear gl. Makes dizzy & can't read.
Been wearing old gl.

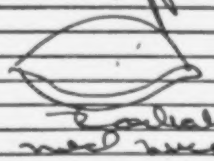
F/up

no gtts.

5-13-88 Still using old car
sees better out of old gl.

V 20/60-
cc 50

OD burns & hurts & [illegible]
Pt. thinks gl. are too strong
[illegible]



[illegible] [illegible]
[illegible] [illegible] [illegible] - [illegible] [illegible]

Put original right lens from Dr [illegible] back into glasses
OD+75-50x52
OS+275-150x100

SUMMARY OF MRS. LM s RIGHT EYE SURGERY -typed 5-4-88

Mrs. M was a remarkably healthy housewife living in , N.C.. She drove her car to church and to shop, worked in her flower garden, was mentally sharp and active. Because of failing vision about Oct 1st. 1986, she saw Dr. (optometrist of . He referred her to the ABC - Eye Associates of , N.C.) She was then age 86, took no cardiac medications, had no diabetes, and was unusually healthy for her age. She took no nerve medicines and rarely saw a doctor.

10-15-86 - Examined by Dr. - ([redacted] opthalmologist) at Eye Assoc.)

10-28-86 - laser iridotomy

Patient scheduled for cataract removal and lens implant at She was given an estimate of expected charges of $2550 (?? 4000) by CEA and $1175 (?? 1775) by of -for a total of $3825.(?? $5775.) Patients daughter (Mrs. -married to a surgeon in ville) accompanied her mother for most of the visits and sat in for the explanations. They were led to believe by assigning Medicare benefits and using supplemental Blue Cross ins., the two insurances would easily cover the costs.

11-24-86 - Dr. extra-capsular cataract removal victrectomy; A-scan biometry; endothelial cell count.

During the process, apparently a piece of the lens cataract dropped back into the vitrous. He advised that she return to , pick up some clothes, and travel to and check in a motel with plans to get the piece of lens removed on the morning of 11-25-86. Mrs. asked if there were "retinal surgeons" in who could do the job since the delay, long trip, pain, and worry would be reduced to a minimum. Dr. told her that they worked with the - group and transferral there would be best. This involved a hurried trip back to packing, change in plans, and a hurried drive to in a blinding rain storm, checking in with the doctor there then on to the motel. The pain, discomfort, and emotional trauma was quite a burden for the 86 year old lady.

11-25-86 Dr.) re-anesthatised in early A.M. reportedly removed the pieces of lens which had been dropped and then Dr. inserted a lens implant. On the P.M. same day, Mrs. was taken to her home in

11-26-86 Dr. - post op visit in

Dec 1, 5, 11, 19, Dr. - post op visits in

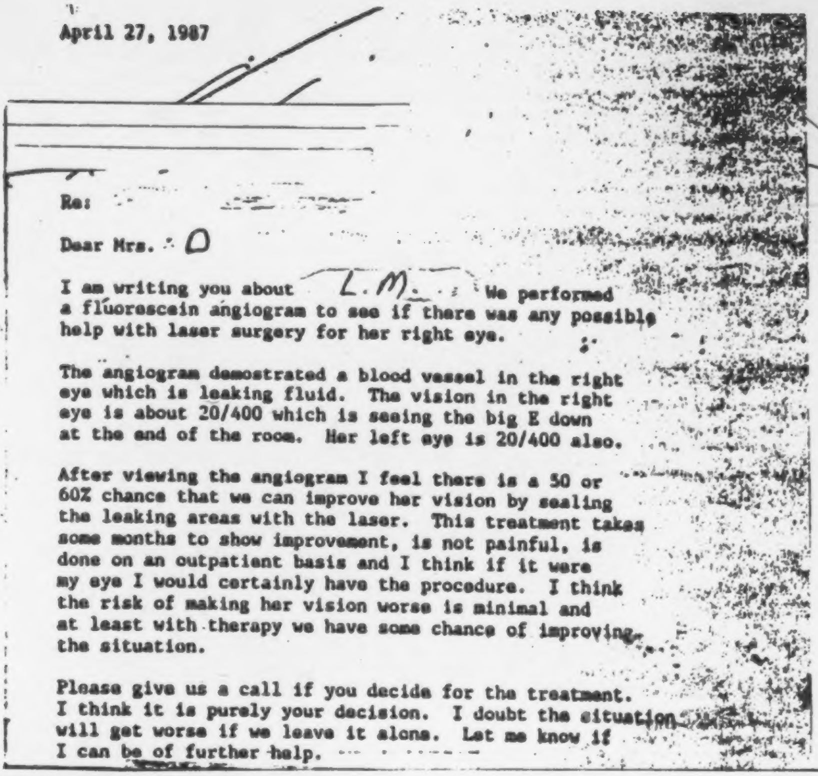
4-6-87 Dr. fluorescene angiography, Fundus photography, UV squid, etc.

Several other visits to including a female optometrist who was quite rude to the nurse and rough to the patient.

Mrs. has never regained satisfactory vision in that eye. When she visited daughter in ville later, appointment made with Dr. of ville who did some laser retinal treatments to that eye. Later she was seen by Dr. - of ville.

Mrs. became quite depressed and discouraged and was unhappy because of the poor results, the many long trips to see the doctors in , the harrassment of the collection agency who tried to collect one of the bills which was dis-allowed by Medicare & Blue Cross. Mrs. had to make 6 or more long trips to to pick her up and take her to . Later she made many trips to bring her to ophthalmologists in Western N.C. after no progress was made in -about 325 miles each R.T. to . The collection agency continued to send nasty letters to Mrs. - long after of N.C.( ) adjusted the balance about [redacted]. April or K 14, 1987.

Another source of patients distress was a guilt complex since she made the decision to get her surgery on the right eye in without consulting her daughter- hoping to save the daughter the time and expense of long trips to WNC. She was influenced by friends and the local optometrist.



April 27, 1987

Re:

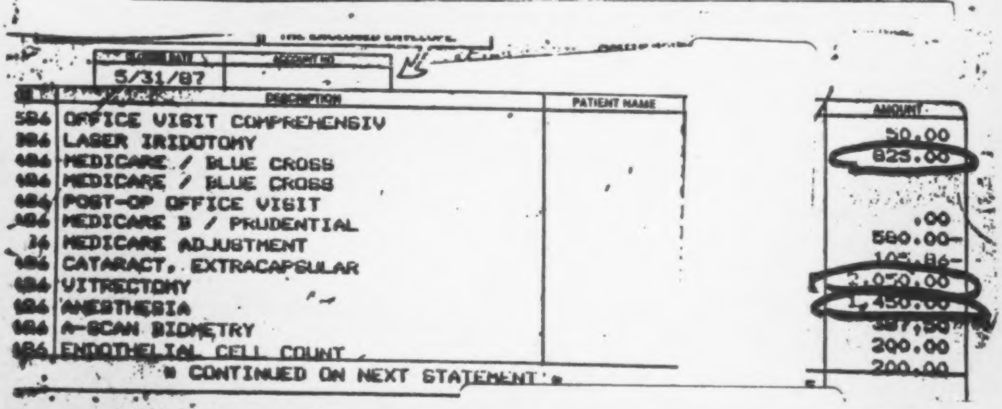
Dear Mrs. O

I am writing you about L.M. We performed a fluorescein angiogram to see if there was any possible help with laser surgery for her right eye.

The angiogram demostrated a blood vessel in the right eye which is leaking fluid. The vision in the right eye is about 20/400 which is seeing the big E down at the end of the room. Her left eye is 20/400 also.

After viewing the angiogram I feel there is a 50 or 60% chance that we can improve her vision by sealing the leaking areas with the laser. This treatment takes some months to show improvement, is not painful, is done on an outpatient basis and I think if it were my eye I would certainly have the procedure. I think the risk of making her vision worse is minimal and at least with therapy we have some chance of improving the situation.

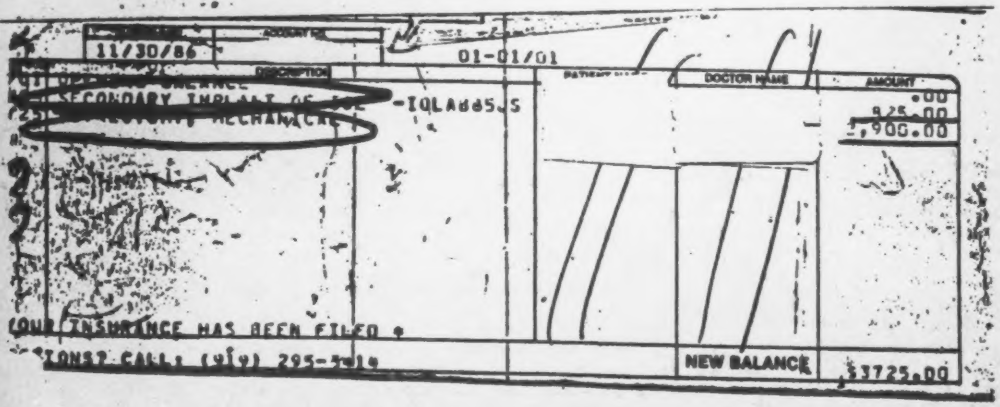
Please give us a call if you decide for the treatment. I think it is purely your decision. I doubt the situation will get worse if we leave it alone. Let me know if I can be of further help.



5/31/87

	DESCRIPTION	PATIENT NAME	AMOUNT
586	OFFICE VISIT COMPREHENSIV		50.00
386	LASER IRIDOTOMY		825.00
486	MEDICARE / BLUE CROSS		
486	MEDICARE / BLUE CROSS		
486	POST-OP OFFICE VISIT		.00
486	MEDICARE B / PRUDENTIAL		580.00-
36	MEDICARE ADJUSTMENT		105.86-
486	CATARACT, EXTRACAPSULAR		2,050.00
486	VITRECTOMY		1,450.00
486	ANESTHESIA		387.50
486	A-SCAN BIOMETRY		200.00
486	ENDOTHELIAL CELL COUNT		200.00

* CONTINUED ON NEXT STATEMENT *



11/30/86

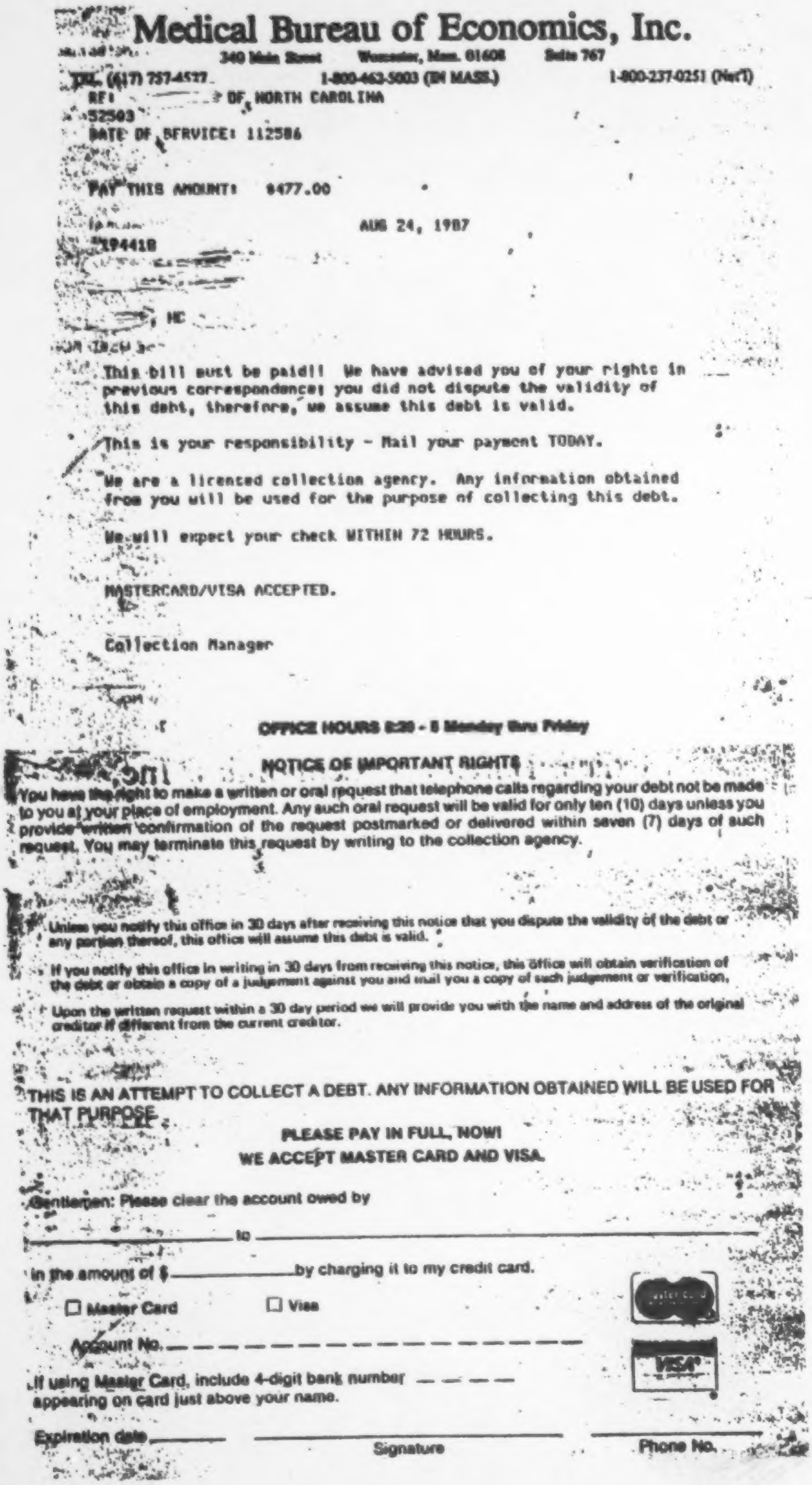
01-01/01

DESCRIPTION		PATIENT NAME	DOCTOR NAME	AMOUNT
[illegible]				.00
SECONDARY IMPLANT OF IOL	-IQLA445.S			825.00
[illegible] MECHANICAL				1,900.00

YOUR INSURANCE HAS BEEN FILED •

IONS? CALL: (919) 295-[illegible]

NEW BALANCE $3725.00



Medical Bureau of Economics, Inc.
340 Main Street Worcester, Mass. 01608 Suite 767
TEL. (617) 757-4577 1-800-462-5003 (IN MASS.) 1-800-237-0251 (Nat'l)

RE: [redacted] OF NORTH CAROLINA
52503
DATE OF SERVICE: 112586

PAY THIS AMOUNT: $477.00

AUG 24, 1987
194418
[redacted]
[redacted], NC

This bill must be paid!! We have advised you of your rights in previous correspondence; you did not dispute the validity of this debt, therefore, we assume this debt is valid.

This is your responsibility - Mail your payment TODAY.

We are a licensed collection agency. Any information obtained from you will be used for the purpose of collecting this debt.

We will expect your check WITHIN 72 HOURS.

MASTERCARD/VISA ACCEPTED.

Collection Manager

OFFICE HOURS 8:30 - 5 Monday thru Friday

NOTICE OF IMPORTANT RIGHTS

You have the right to make a written or oral request that telephone calls regarding your debt not be made to you at your place of employment. Any such oral request will be valid for only ten (10) days unless you provide written confirmation of the request postmarked or delivered within seven (7) days of such request. You may terminate this request by writing to the collection agency.

Unless you notify this office in 30 days after receiving this notice that you dispute the validity of the debt or any portion thereof, this office will assume this debt is valid.

If you notify this office in writing in 30 days from receiving this notice, this office will obtain verification of the debt or obtain a copy of a judgement against you and mail you a copy of such judgement or verification.

Upon the written request within a 30 day period we will provide you with the name and address of the original creditor if different from the current creditor.

THIS IS AN ATTEMPT TO COLLECT A DEBT. ANY INFORMATION OBTAINED WILL BE USED FOR THAT PURPOSE.

PLEASE PAY IN FULL, NOW!
WE ACCEPT MASTER CARD AND VISA.

Gentlemen: Please clear the account owed by
________________ to ________________

in the amount of $____________ by charging it to my credit card.

☐ Master Card ☐ Visa

Account No. _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

If using Master Card, include 4-digit bank number _ _ _ _
appearing on card just above your name.

Expiration date ________ ____________ Signature ____________ Phone No.

This bill was discussed with the person in charge - 3 or 4 times we were told to ignore the letters (billings) The threatning Collection letters upset the patient dreadfully - often she called in tears about it - Many Calls & Many Months & a letter finally Closed the matter - Harassment to the limit!

"The bills were coming in many times after telling us there were no more bills - That amt. was Cancelled

CASE 4:

May 13, 1988

Re: T.B.

Summary:

T.B. is a seventy six year old male, who consulted me on July 30, 1986 for a second opinion regarding cataract surgery. Mr. T.B. had been seen by an optometrist who told him he had significant cataract formation and that he needed surgery. He refered him to Dr. for cataract surgery. It is my understanding that Mr. T.B. was scheduled for surgery without having been seen by Dr.

Examination of Mr. T.B. revealed minimal cataract formation which would have decrease his visual acuity to no more than 20/25. He did have evidence of age related macular degeneration, which caused the decrease in his vision in the right eye to 20/60 and the left eye to 20/40. In addition to my self the patient was also seen by Dr. who also agreed that Mr. T. B.'s problem did not consist of cataracts, but of age related macular degeneration instead.

CASE 5:

B

CASE REPORT

I first examined Ms. R.W. in February of 1982. At that time, her vision was 20/30 in each eye. She was noted to have mild macular degeneration. She was not seen again until August of 1986, at which time her visual acuity was best corrected to 20/50- in the right eye and 20/40 in the left. She had had cataract surgery with a lens implant in the left eye performed by Dr. T. in December of 1984. She had been followed by an optometrist, Dr. H. intermittently since 1974 with visual acuities in the 20/30 - 40 range. She was seen in November of 1984 by this optometrist, and found to have 20/40 vision in the right eye and 20/200 vision in the left. No attempt was made to refract the patient. The macular degenerative changes were noted and the patient subsequently referred to Dr. M., a retinal specialist. During his evaluation, which included uncorrected visual acuities and pin hole refraction, she as well was found to have potential acuity meter readings of 20/30 and 20/50. She was described to have had minimal lens changes. She was urged to have cataract surgery, which she subsequently had in December of 1984. Subjectively, she did not note improvement. At the time, she had been seen in 1982 there were no lens changes noted, and as of 1986, there were still only minimal changes in the right eye, and of course the lens implant in the left. The cataract in the right eye has continued to progress, and in May of 1988, with visual acuities of 20/100- in the right eye best corrected, and 20/70+, she has undergone cataract extraction with a lens implant in the right eye and YAG capsulotomy on the left. Potential acuity meter readings at this time were 20/30- and 20/40+.

This case is representative of a patient with macular degeneration which was actually noted by the optometrist and referred to a retinal specialist who noted that, but as well, referred the patient for cataract surgery. At no time was a manifest refraction done; subsequently cataract surgery was done at the very least, prematurily and was noted both by the numbers and subjectively by the patient to have been of little benefit at the time.

, M.D.

CASE 6:

A

#393328

75 year old female was seen 12/19/85, having been seen by a local optometrist and advised to have her cataracts removed at a regional high volume center. She did not wish to have her cataracts operated and, in fact, stated that she would not have known of cataracts or any problems with her eyes if she hadn't been told so by the local optometrist.

Vision with refraction revealed 20/30- acuity each eye, 20/30 both eyes.
SLIT LAMP: Showed early nuclear sclerosis.
No other pathology was found.

She has been followed since that time developing a macular pucker on the right reducing her vision to 20/300. The cataracts have only minimally progressed and her vision remains 20/30- in her left eye, 20/200 on the right. That vision is down because of the macular pucker.

Her last visit was 4/20/88

CASE 7:

May 13, 1988

RE: P.B.

Summary:

Mr. P.B. is a sixty three year old male who was diagnosed as having glaucoma by an optometrist approximately three years ago. He was followed by this optometrist for two years, being treated with various medications. He was subsequently referred to Dr. N.C. who told the patient that his glaucoma was not well controlled and that he also had cataracts that needed surgery immediately. The patient was informed that after he had the cataract surgery that it would no longer be necessary to use eye drops, that the the surgery would cure his glaucoma. Accordingly, Mr. P.B. had cataract surgery on his left eye, possible combined with a glaucoma procedure. Post-operatively, however, the pressure in the left eye did go back up and because there was some discrepancy in what Dr. told the patient and what the optometrist who had referred him to Dr. had told him, the patient decided to have a third opinion. He consulted me approximately six months ago and was found to have evidence of chronic open angle glaucoma in both eyes. He had minimal lens changes in his right eye. Visual acuity 20/25. Dr. had told him only a few weeks before that he needed cataract surgery very badly on this eye and had made arrangements to do this. The left eye showed evidence of cataract surgery with a posterior chamber intraocular lens implant and visual acuity was 20/20 in that eye.

It was quite obvious to me that the patient did not need cataract surgery in his right eye and if it had been done this would have constituted unnecessary surgery.

It is also interesting to note that the patient stated that the optometrist charged him over $200.00 for his post-operative care following cataract surgery by Dr.

CASE 8:

A

May 13, 1988

Re: E.H.J.

Summary:

Mrs. E.H.J. saw an optometrist in the summer of 1986, who told her she had advanced cataracts and needed cataract surgery immediately. This optometrist in town, North Carolina called Dr. office in , North Carolina and arranged a specific date and time for the patient to have cataract surgery at the Eye Clinic. Because of the rapidity with which this matter was handle and because the patient was hardly consulted regarding her wishes concerning this matter the patient and her family became quite upset and consulted me for a second opinion.

Upon examination of Mrs. E.H.J. she was found to have minimal lens changes and certainly did not have significant cataract formation. She had some vision loss related to macular degeneration and also showed evidence of chronic open angle glaucoma which was undiagnosed. I have been following the patient for the last two years and she still does not have any significant cataract formation. She is under treatment for her medical eye problems.

CASE 9:

B

May 10, 1988

[redacted], M.D.
[redacted]

Dear Dr. [redacted]

Thank you for your inquiry regarding patient J.R., a 69 year old gentleman who presented to me self-referred in December 1986 stating that he had been scheduled for a cataract surgery and wanted a second opinion. His chief complaint was mildly blurred vision, four years duration, with some distortion of vision at near. He is a retired police officer.

My examination demonstrated a visual acuity which was best corrected to 20/20 OD and 20/20 OS with refractions of -0.25 -1.50 x 150 OD and plano OS. Near vision was J2 OU improving to J1 with an overcorrection of +0.50. His intraocular pressure was 10 in each eye. The pertinent findings in the remainder of his examination were the presence of very minimal lens change with a clear view of the fundus by Hruby lens examination and a conclusion that his symptoms were due principally to presbyopia, recommending a change in the near correction present in his glasses.

Patient J.R. was able to function very well in every aspect of his life and in fact, as a hobby worked with high speed precision power equipment making furniture. He volunteered that he was functioning well and had no visual complaints that he considered to be significant. He had turned to an ophthalmologist who had been in practice in his community and has recently earned an increasing reputation as a cataract surgical specialist. The patient related that the surgery had been recommended based on his chief complaint of distorted near vision. I subsequently spoke with the ophthalmologist who had recommended surgery and he noted that he had recommended surgery based on glare testing which demonstrated, under simulated conditions, lesser vision. I questioned patient J.R. regarding glare and this was not a notable symptom to him.

I advised the patient that I did not feel surgery was indicated and recommended that he seek continuing care from one of several other ophthalmologists in the community. I have since spoken with the ophthalmologist who is following the patient who reports that he continues to have vision of 20/20 OD and 20/30 OS with minimal cataract change and no evident impediment to his function. I felt that the lens changes that were present were quite acceptable for what one would find in the normal population at this age and in the absence of any functional disturbance that the patient could defer surgery until more prominent symptoms were caused by the slowly progressive cataract change.

Please let me know if further information is desired.

Sincerely yours,

CASE 10: D

[redacted] M.D.
[redacted]
BOARD OF OPHTHALMOLOGY

[redacted]

NARRATIVE SUMMARY

I have seen multiple patients who were told that they needed cataract surgery. They were told that they would "go blind" if cataract surgery was not performed. They were also told that the operation would be much more difficult if they waited too long. This is a very common senario and has been seen by me at least twenty times in the past several years.

CASE 11: B

[redacted] M.D.
DIPLOMAT, AMERICAN
BOARD OF OPHTHALMOLOGY

[redacted]

NARRATIVE SUMMARY

This 66 year old white male retired policemen was seen by a high volume ophthalmologist and was given a new pair of glasses. Within several weeks the patient returned complaining of decreased vision with the new glasses. The high volume ophthalmologist then recommended cataract surgery and actually did the preliminary test including A-Scan Biometry to perform the surgery. The patient saw a friend who recommended that he seek a second opinion. This second opinion was obtained and the second ophthalmologist found a vision of 20/20 in the right eye with no optical correction necessary. A Third opinion was sought from a subspecialist at [redacted] Eye Center, [redacted] who confirmed that no cataract was present and certainly did not recommend any surgery. Incidently, the patient had absolutely no visual complaints except for blurred vision with new glasses. The glasses were not plano but had some astigmatism correction which obviously was unnecessary.

CASE 12: A-

SUMMARY

[redacted]

NCBH # 45 79 29
DOB: [redacted]
SS#: [redacted]

Mrs. [redacted] was seen by me on April 3, 1987. At that time she gave the history that she is a 50 year old lady who had carried her mother to the [redacted] Eye Associates in [redacted] for evaluation and management of cataracts on referral from her mother's optometrist. Mrs. [redacted] and her sister had carried their mother to [redacted] and were sitting together in an examining room with their mother who was sitting in the examining chair. Mrs. [redacted] and her sister were sitting in chairs which had been placed there in the room for family members. As Dr. [redacted] walked into the room he looked at her across the room, told her she had short eyes and angle closure glaucoma and should have laser surgery. She said her response was one of complete shock and surprise. After having examined her mother, Dr. [redacted] asked her to sit in the examining chair and examined her and said that yes, indeed, she did have short eyes and angle closure glaucoma and should have laser surgery. This was arranged to be carried out two days after this meeting at the same time her mother was to have her cataract surgery done. After she arrived home, she became concerned and called her local ophthalmologist here in [redacted] regarding this and he referred her to me for another opinion. She denies any prior ocular injury. She says she has never had any symptoms of pain, blurred vision or halos around lights with either eye. The family history shows that she has a mother and maternal grandmother with cataracts. There are two maternal aunts with glaucoma, the type of which she is not aware. She was on no medications at the time I saw her.

Her vision on that visit was 20/20 in each eye at distance with her current correction. I refracted her and found the correction which she was wearing to be essentially correct. That is I found her to need a +2.00 -.50 x 120 in the right eye and a +2.25 in the left eye. Each of these yielded 20/20 vision at distance. Her intraocular pressure that day at 10:53 a.m. was 15 in each eye. The pupils were normal as was the slit lamp examination. Specifically, the anterior chambers were deep and quiet and there was no evidence of iris atrophy. On gonioscopy there was a moderate amount of peripheral iris convexity, but the spur and anterior ciliary body band were visible throughout the angle and there was no iris angle apposition or peripheral anterior synechiae noted. Ophthalmoscopy through the undilated pupil showed a very normal appearing optic nerve head cup and the posterior pole was otherwise unremarkable. I placed her in a dark room for one hour and the intraocular pressure did not rise in either eye. Specifically, the intraocular pressure began at 15 in the right and remained 15 in the right after an hour and 10 minutes and in the left went from 13 to 16. Gonioscopy following this showed no change in the appearance of the angle.

My impression is that Mrs. has mild hyperopic astigmatism, but does not now appear to have and does not show evidence of previously having had angle closure glaucoma. We had discussed the symptoms of angle closure glaucoma and I instructed her that if she should experience any of those she should seek immediate ophthalmologic attention. My recommendation was that she not have laser iridotomy. She is to be followed by her local ophthalmologist.

CASE 13: β

PATIENT: #324
AGE: 57
RACE: Caucasion
SEX: Female
HISTORY: This patient stated that in 1984 Dr. had told her she had a cataract and that he wanted to remove the left one first and then do the right. On last examination (Dec. 8, 1986) her acuity was 20/20 O.U. best corrected. There were a few peripheral cortical spokes in the right lens and a petaloid opacity in the superior cortex of the left lens. The lens were otherwise normal. She had no vision related complaints.

20MACP

CASE 14: B

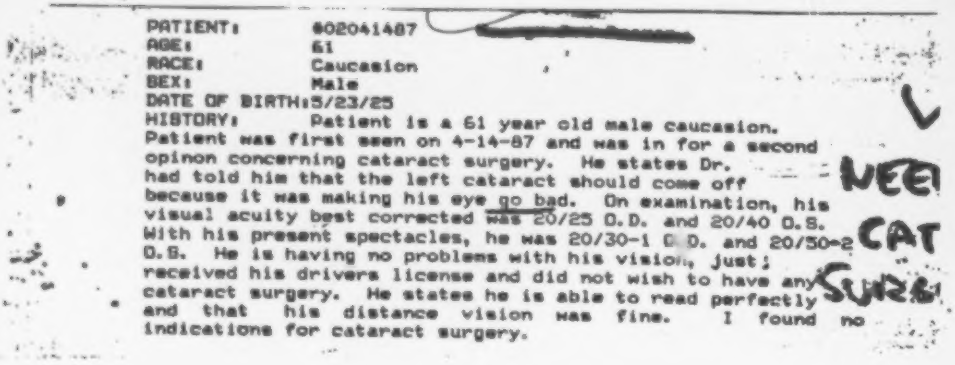
[redacted]

PATIENT: #06081085
AGE: 66
RACE: Caucasion
SEX: Female
HISTORY: This lady first consulted me August 10, 1985 for a second opinion for cataract surgery recommended by Dr. She did not wish a complete exam but needed a second opinion for insurance. She was noted to have nuclear sclerosis O.U. She returned on September 9, 1986 with no visual complaints and had had the left cataract removed already. She said she saw no better and was having no problems with her vision but that Dr. wanted to do the other cataract and had said that it would not cost her anything. Her visual acuity best corrected was 20/50+3 O.D. and 20/30 O.S. Dilated fundus exam showed macular drusen. I informed her the cataract surgery was not necessary.

TOLD NEEDED CAT,
[illegible]
✓

CASE 15:

B



PATIENT: #02041487 [redacted]
AGE: 61
RACE: Caucasion
SEX: Male
DATE OF BIRTH: 5/23/25

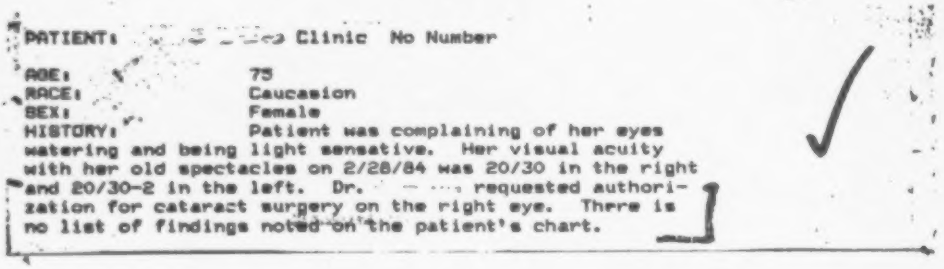
HISTORY: Patient is a 61 year old male caucasion. Patient was first seen on 4-14-87 and was in for a second opinon concerning cataract surgery. He states Dr. had told him that the left cataract should come off because it was making his eye go bad. On examination, his visual acuity best corrected was 20/25 O.D. and 20/40 O.S. With his present spectacles, he was 20/30-1 O.D. and 20/50-2 O.S. He is having no problems with his vision, just received his drivers license and did not wish to have any cataract surgery. He states he is able to read perfectly and that his distance vision was fine. I found no indications for cataract surgery.

✓

NEE
CAT
SURG

CASE 16:

D



PATIENT: Clinic No Number

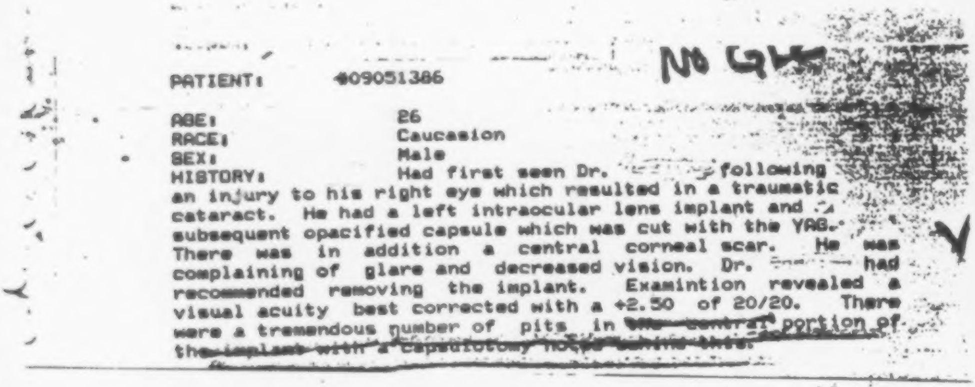
AGE: 75
RACE: Caucasion
SEX: Female

HISTORY: Patient was complaining of her eyes watering and being light sensative. Her visual acuity with her old spectacles on 2/28/84 was 20/30 in the right and 20/30-2 in the left. Dr. requested authorization for cataract surgery on the right eye. There is no list of findings noted on the patient's chart.

✓

CASE 17:

B



NO GH

PATIENT: #09051386

AGE: 26
RACE: Caucasion
SEX: Male

HISTORY: Had first seen Dr. following an injury to his right eye which resulted in a traumatic cataract. He had a left intraocular lens implant and subsequent opacified capsule which was cut with the YAG. There was in addition a central corneal scar. He was complaining of glare and decreased vision. Dr. had recommended removing the implant. Examintion revealed a visual acuity best corrected with a +2.50 of 20/20. There were a tremendous number of pits in ~~the central~~ portion of th~~e implant with a capsulotomy notch behind this.~~

✓

CASE 18: A

CASE REPORT #14-59-51

GB, a 68 year old black female was seen in the office of her local ophthalmologist on 10/28/86 for a second opinion. This patient stated that she had recently been seen in the office of her local optometrist who informed her that she had a cataract in the left eye which required immediate surgical intervention. This patient was told that she should have the surgery performed at a high volume surgical center in Eastern North Carolina as soon as possible. The patient did not wish to leave town for medical care and felt that her vision was not poor enough to warrant immediate surgical attention. The patient, therefore, sought a second opinion.

Upon examination, the patient was found to have visual acuity with her present glasses of 20/40 minus 2 in the right eye and 20/40 minus 2 in the left eye. Refraction showed that the patient's vision could be improved to 20/40 plus 1 in the right eye and 20/40 minus 2 plus 3 in the left eye. With both eyes open, the patient read a fairly brisk 20/30 minus 2 vision and with a proper reading add, the patient saw a brisk 20/20 with both eyes open at near. Biomicroscopic examination did show moderate nuclear sclerotic and cortical cataract in both eyes. The remainder of the ophthalmic examination was unremarkable for this patient. The patient was informed that with a minor glasses change she could be improved to 20/30 vision which was adequate for unrestricted driving privileges in the state of North Carolina. The patient replied that she definitely did not want any surgery on her eyes if it could be avoided and that as long as she could drive in an unrestricted fashion, she was happy to simply change her glasses and go on about her business. The patient also reported that she was having absolutely no difficulty with her daily life tasks and functions and that her vision was not handicapping her in any way. The patient's glasses were changed and she was discharged to be followed up at yearly intervals.

This patient was re-examined by her local ophthalmologist on 4/5/88 and was found to be suffering from moderate advancement in the cataracts in both eyes. Her best corrected visual acuity had decreased to the 20/70 minus 2 level in the right eye and 20/50 minus 2 level in the left eye. The patient now was indeed complaining of difficulty with her vision and was desirous of improved visual acuity in the right eye. The patient subsequently underwent cataract extraction with implantation of an intraocular lens in the right eye later in April of 1988 and has done well since that time.

As can be seen, this elderly patient was able to postpone purely elective surgery for her cataracts until such time as she felt she was visually handicapped. This patient was led to believe that surgery was needed urgently when she was first evaluated by her referring optometrist and this proved not to be the case. Elderly patients often defer elective surgery until such time that there vision becomes functionally disabling in some manner. This is entirely appropriate. It is inappropriate for elderly patients to be routinely considered for cataract surgery with vision at the 20/40 level. 20/40 vision is adequate for unrestricted operation of a motor vehicle in all 50 states of the Union - an act synonymous with independent living by most elderly people. Patients with 20/40 cataracts simply do not need "urgent" cataract surgery.

CASE 19: B

CASE REPORT #00-45-02

AM, a 69 year old white female was seen by her local ophthalmologist in North Carolina on 11/12/86. This patient had recently been seen in the office of a high volume surgeon in Eastern North Carolina where she was told that she needed cataract surgery and that she had glaucoma in both eyes. The patient had been placed on antiglaucoma medication but had decided to discontinue it on her own 1½ weeks prior to the visit with her local ophthalmologist. Upon examination it was found that she had mild nuclear sclerotic and mild posterior subcapsular cataract in the right eye and a clear lens in the left eye. Her best corrected visual acuity was 20/30 minus 2 in the right eye and 20/25 minus 3 in the left eye. The patient's bright light (glare testing) visual acuity in the right eye was unchanged at 20/30 minus 2. The patient's intraocular pressure was 14 on the right and 16 on the left. Post dilation intraocular pressures showed 17 on the right and 15 on the left. Fundus examination showed no evidence of glaucomatous cupping in either eye. Visual field examination was full in either eye. The patient was informed that she did not have significant cataract or glaucoma in either eye and did not need surgery or antiglaucoma medication in either eye. The patient's glasses were changed and she was sent on about her business.

The patient was seen for routine follow-up six months later on 5/12/87 where a mild increase in the cataract in the right eye was noted. The patient's vision could be improved to the 20/40 minus 1 plus 2 in the right eye and 20/30 minus 2 in the left eye with a minor glasses change. With both eyes open the patient could see 20/30 plus 2 with her new glasses. The patient's intraocular pressures were normal at 17 in either eye. The patient was given a minor lens change and was sent on about her business.

The patient returned for follow-up ten months later on 3/11/88 at which time she complained of further decreasing vision in the right eye with difficulty reading and driving at night. Examination showed an increase in the posterior subcapsular cataract of the right eye. Her bright light visual acuity now showed a marked decrease to the 20/100 minus 2 level. The patient was deemed to be a suitable candidate for cataract extraction with implantation of an intraocular lens in the right eye which was accomplished in late March of 1988. The patient has since completed her recovery period and has had an excellent visual result in the right eye. Her intraocular pressure has been normal at multiple visits per her local ophthalmologist over the last two years.

In summary, we have a 69 year old white female who was told at a high volume surgery center that she "needed" cataract surgery and had glaucoma in both eyes. The patient has since been shown to definitively not suffer from glaucoma in either eye and her initial cataract diagnosis was extremely premature. This patient had 20/30 vision in the right eye and 20/25 vision in the left eye when she was seen by her local ophthalmologist for second opinion. Patients with this kind of visual acuity are simply not candidates for cataract extraction except in extremely unusual circumstances (airline pilots, professional football quarterbacks, etc.) This patient was able to defer her surgery for almost a year and a half until her cataract became visually disabling and she subsequently underwent a successful elective procedure.

CASE 20: B

CASE REPORT #12-77-77:

GBL is an 82 year old black female from Eastern North Carolina well known to the ophthalmic practice of her local ophthalmologist since 1965. This lady had had poorly controlled glaucoma for many many years and upon examination on 2/22/80 it was found that her vision had decreased to light perception only in the right eye and no light perception in the left eye. This level of visual impairment was repeatedly documented in visits throughout 1980 and 1981 and subsequent years. The patient was referred to another local ophthalmologist for a second opinion about her end stage glaucoma process in both eyes. That examination on 2/16/81 confirmed that the patient had an extremely poor visual acuity in both eyes as listed above. Examination of her optic nerves showed marked cupping of both nerves with the right eye specifically measuring 0.95 with a very thin neural rim. This physician recommended increasing her topical medication but did not recommend cataract extraction for her.

Pt. GLB was left with essentially blind eyes due to glaucoma for the next several years until she was encouraged to seek treatment at one of the high volume cataract centers in North Carolina. Obviously, this woman was anxious to achieve some sort of return of useful vision and sought treatment at this high volume center because she was under the impression that "they work miracles". This patient traveled two hours to this high volume center and was told that she could be helped with a cataract operation and placement of an implant in her right eye. This patient had the operation later that day and returned home the following day for convalescence. When the patient returned for her follow-up examination at this high volume center, it was noted that she had achieved no improvement in vision. She was then subjected to a Yag laser posterior capsulotomy procedure with no improvement in her vision. On a subsequent visit she was subjected to an Argon laser trabeculoplasty in the right eye - again with no improvement in her vision. At this point, the patient and her niece were informed that nothing further could be done for the eye and the patient was discharged from the care of this high volume center.

All three of these above listed surgical procedures were definitively unnecessary for this unfortunate woman. Medical records existed documenting her care and treatment for many years by her local ophthalmologist. Her optic nerves had been damaged severely by glaucoma and as early as 1980, it was apparent that she had a potential for only bare light perception vision in the right eye. Cataract extractions are simply not indicated in these patients. A simple phone call or release of medical records to the local ophthalmologists would have provided definitive evidence that cataract surgery would be of no benefit to this patient. Instead of waiting to obtain medical records or phoning her local ophthalmologist, the high volume surgeon decided to proceed with immediate surgery regardless of its potential for improving this unfortunate lady's situation. The subsequent laser surgeries were definitively unnecessary in that the surgeon most certainly would have been able to visualize the optic nerve after the initial cataract operation and determine that her optic nerve was destroyed by glaucoma. In addition, this high volume surgery center is well known to have in its possession an instrument known as a potential acuity meter which will measure the potential for vision in these patients. It is interesting that this instrument was not employed usefully before the cataract operation or before the Yag laser capsulotomy for this patient. Lastly, the Argon laser trabeculoplasty is definitively unnecessary for a patient of this type in that her intraocular pressures have been well controlled for many years when she is on a proper dose of medication and using it properly. Indeed, this patient was only on one medication at the time of her evaluation and surgery at the high volume surgery center.

This patient has been followed by another ophthalmologist in her local community since this operation and this doctor has documented the patient GBL's vision in the right eye remains at light preception in the right eye. The patient's niece confirmed that this patient attained absolutely no improvement in her vision from any of these three procedures. This "cut now - ask questions later" approach to elderly Medicare patients is all too common in high volume surgery centers. It can be realistically estimated that Medicare spent between $6,500.00 and $7,000.00 for the unnecessary procedures which this unfortunate patient underwent.

CASE 21: A

CASE REPORT #09-96-56

HE, a 70 year old black female was seen by her local family practitioner on 6/9/86. This patient reported that her local optometrist had scheduled her for cataract surgery through the office of an ophthalmologist in Central North Carolina. The family practitioner noted that her visual acuity was fairly acceptable in his office and that he could visualize the fundus fairly well in both eyes. The patient had other medical problems including morbid obesity, hypertensive cardiovascular disease, and borderline control of essential hypertension. The family practitioner felt the patient had acceptable visual acuity at the time of this examination and that she should seek a second opinion.

The patient was referred to the office of her local ophthalmologist on 6/13/86 for second opinion re. cataract surgery. The patient stated that she had been scheduled for cataract surgery on her right eye by her local optometrist. The patient was asked as to whether she was having any particular difficulty with her eyes or vision. The patient stated that she had no real difficulty with her vision but was informed by her referring optometrist that surgery was necessary. The patient stated that she did not want surgery if it was avoidable. Examination in the clinic showed a totally normal ophthalmic examination except for some early cortical and posterior subcapsular cataracts in both eyes. The patient's best corrected visual acuity could be improved to the 20/25 minus 3 level in the right eye and the 20/25 minus 3 level in the left eye. With both eyes open the patient saw a brisk 20/25 plus 2. With an appropriate reading add, the patient could see 20/20 with either eye at near. The remainder of the ophthalmic examination and fundus examination were entirely normal. The patient was informed that she had very mild cataracts in both eyes and did not need surgical intervention at this time. The patient was very relieved to hear this and obviously opted to have her glasses changed instead of an operation.

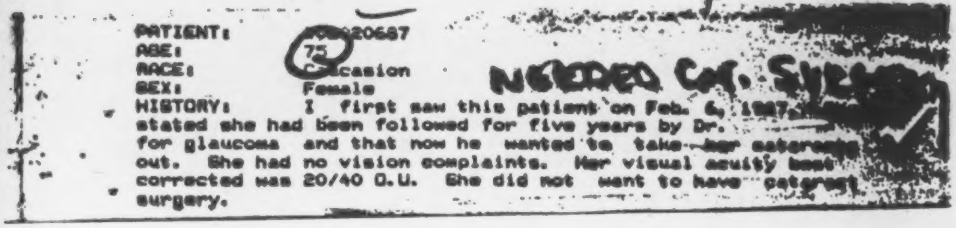
Patient HE's local ophthalmologist contacted the office of the surgeon in central North Carolina who was scheduled to perform patient HE's surgical procedure. Her local ophthalmologist spoke with office personnel from the second office and confirmed that the patient had indeed been scheduled for cataract surgery by her referring optometrist and that the second surgeon was expecting patient HE in the office later that day for cataract surgery. Both patient HE and the office personnel confirmed that the patient would be returned to her local optometrist for postoperative care.

Patient HE has been seen in the office of her local ophthalmologist on two occasions since June of 1986 at which time she has been found to be suffering from minimal cataracts in either eye. Patient HE was last seen on 4/19/88 at which time her vision with present glasses had decreased to the 20/60 minus 2 level in her right eye and 20/50 minus 2 level in the left eye. Biomicroscopic examination confirmed moderate advancement of her cataracts in both eyes. With a proper refraction the patient could be returned to 20/40 minus 1 vision in the right eye and 20/30 minus 2 vision in the left eye. The patient was delighted to have the improvement in her vision through a refractive means and was again informed that she did not need cataract surgery. This elderly patient has been discharged with a new pair of glasses and will be seen again at 9 to 12 month intervals.

Again, we see an elderly patient informed that she "needs" cataract surgery when this is simply not the case.

CASE 22:

B

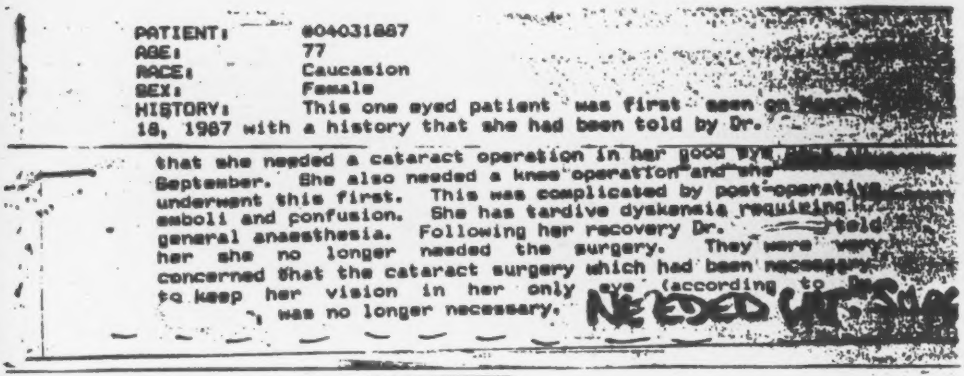


PATIENT: [illegible]20687
AGE: 75
RACE: [illegible]casion
SEX: Female
HISTORY: I first saw this patient on Feb. 6, 1987. [illegible] stated she had been followed for five years by Dr. for glaucoma and that now he wanted to take her cataracts out. She had no vision complaints. Her visual acuity best corrected was 20/40 O.U. She did not want to have cataract surgery.

NEEDED CAT. SUR

CASE 23:

B



PATIENT: #04031887
AGE: 77
RACE: Caucasion
SEX: Female
HISTORY: This one eyed patient was first seen on [illegible] 18, 1987 with a history that she had been told by Dr. that she needed a cataract operation in her good eye [illegible] September. She also needed a knee operation and she underwent this first. This was complicated by post-operative emboli and confusion. She has tardive dyskensia requiring general anaesthesia. Following her recovery Dr. told her she no longer needed the surgery. They were very concerned that the cataract surgery which had been necessary to keep her vision in her only eye (according to Dr.), was no longer necessary.

NEEDED CAT. SUR

CASE 24:

B

CASE REPORT #09-40-73

DM, a 78 year old white female was seen in May of 1987 by a high volume surgeon in Eastern North Carolina who informed this patient that she was in imminent danger of angle closure glaucoma and was in need of bilateral peripheral iridectomies and then cataract extraction in both eyes. Her local ophthalmologist reviewed the office notes from the high volume surgeon and found that the patient was recorded as having complained of visual impairment. The patient stated to her local ophthalmologist that she was having no difficulty driving or reading and was concerned about the necessity of procedures for both eyes. Very briefly, she was found to have a minimal nuclear sclerotic cataract in either eye. Her anterior chamber angles were deeply open by both biomicroscopy and gonioscopy. Her intraocular tension was normal at 16 in either eye. The fundus examination showed moderate senile macular degeneration consistent with the patient's age. The patient was refracted and it was discovered that her vision could be improved to 20/40 in the right eye and 20/30 plus in the left eye - a level consistent with unrestricted interstate day or night driving. The patient's eyes were dilated and her gonioscopy was performed again - showing open anterior segment angles with no danger of occlusion and normal post dilation intraocular pressures. A driver's license card was produced by the patient which had been filled out by the high volume surgeon and it was indicated on this card that the patient's best corrected visual acuity was 20/60 in the right eye and 20/100 in the left eye. This information was false and untrue, as the patient was okay for unrestricted driver's license. The patient was reassured that she was not in need of any glaucoma or cataract surgery, and she simply needed to have her glasses changed.

In summary, we have an elderly white female who is informed that she needed immediate glaucoma and cataract surgery to preserve her vision who was found on subsequent examination to not have glaucoma in either eye or a significant cataract in either eye. The patient had been totally misled as to the level of her visual impairment and was capable of vastly improved visual acuity with a simple glasses change.

CASE 25:

A

CASE REPORT #15-20-09

JNC - 65 year old white male who was seen by his local optometrist in Eastern N. C., and was informed that he had a cataract in the rt. eye which required surgical attention. Patient was scheduled for surgery on this right eye at the office of a high volume surgeon in Eastern N. C. The pt. desired a second opinion and sought consultation at the office of an ophthalmologist in his hometown. At that visit the diagnosis of cataract was made and the pt.'s best corrected visual acuity was noted to be count fingers at one foot in the rt. eye. The patient was indeed felt to be a candidate for cataract extraction and was counseled as to the risks and benefits of cataract surgery. The patient opted to have his surgery performed in his hometown by his local ophthalmologist as he did not wish to travel out of town for surgery at a high volume center. The pt., therefore, consented to and was scheduled for cataract surgery per his hometown ophthalmologist.

Before pt. JNC underwent surgery per his local ophthalmologist, he was contacted by the optometrist who had initially seen him. The optometrist was distressed that that pt. had decided to seek treatment locally and tried to persuade the patient to cancel his surgery per his local ophthalmologist and seek cataract surgery at the high volume referral center out of town. This sequence of events was reported to the local ophthalmologist by pt. JNC and his family. An appropriate entry was made in the medical records concerning the attempt by the local optometrist to have the pt. cancel his locally scheduled surgery and seek surgical attention at a high volume referral center.

It should be noted that the local ophthalmologist and local optometrist had never had any substantive referral arrangement, as the optometrist in question refers virtually all of his cataract surgery patient out of town to high volume surgeons who will then return the pt. to the local optometrist for postoperative care - to include a "postoperative care fee". This case illustrates the length to which some optometrists will go to direct patients to certain providers pursuant to an arrangement, whereby the referring optometrist is to receive a fee generating opportunity when patients are referred for surgery.

CASE 26:

B

PATIENT: #06050785
AGE: 94
RACE: Caucasion
SEX: Female
HISTORY: First seen on May 7, 1985 she was very upset that she had been told by Dr. that she needed to have her right eye operated on for a cataract. She had had a left cataract extraction with a subsequent central retinal vein occlusion and hen visual acuity in this eye was 10/400 best corrected. Her visual acuity in her good eye was 20/60 with her present spectacles and she felt this was adequate vision.

✓

CASE 27: B

PATIENT: #01021486

AGE: 51
RACE: Caucasion
SEX: Male
HISTORY: Patient had been told by Dr. that he had a touch of glaucoma and needed laser treatment on his right eye. He had no history of glaucoma and never used any drops. He had no family history of glaucoma. He is using Nitroglycerin for circulation problems and attacks of angina. On examination on February 14, 1986, his intraocular pressures were 21 in the right and 20 in the left. His visual acuity was 20/20 O.U. Gonioscopy showed deep and symmetrically visable angles, mild pigment. The right optic disc was markedly asymmetric with a cup to disc ratio of 0.6 and the left about 0.3. There is a slight posterior subcapsular cataract on the right. Subsequent intraocular pressures were 19 and 16, and 18 O.U. on no medication. He is being followed.

✓

LASER AS 1° TX.
NO GLC.

CASE 28: D

PATIENT: #03012486

AGE: 21
RACE: Black
SEX: Female
HISTORY: No family history for glaucoma or blindness or eye disease. Patient was first seen on January 24, 1986 complaining of headaches and her eyes hurting and wearing a -8.00+ 2.50 x 145 O.D. and a -4.75 + 4.75 x 40 O.S. refraction. She stated Dr. told her she had a cataract in her right eye. On examination, her visual acuity with her present spectacles was 20/400 O.D. and 20/70 O.S. She had keratoconus. Her lenses were crystal clear. Her left eye is fitted with a contact lens and she is 20/20. The right eye is being fitted. There was no evidence for cataract. Her vision uncorrected was 20/400 O.D. and 20/70 O.S.

✓

TOLD NEEDED CAT.
SURGERY
HAD KERATOCONUS

CASE 29:

B

[redacted]

PATIENT: #05110685

7/20 Cataracts

AGE: 66
SEX: Male
RACE: Caucasion
HISTORY: Patient had a right cataract surgery by Dr. with an intraocular lens in July of 1985. He stated he was not having any problem prior to the surgery. He was well pleased with the results, however, and was scheduled for a left cataract and intraocular lens in January of 1986. His prescription in the right eye was plano -0.75 x 180 and in the left eye was -2.25 -0. 50 x 20. He was complaining of depth perception irregularity without his glasses and did not like wearing his glasses. There was a mild amount of nuclear sclerosis and his visual acuity with his present spectacles was 20/25 in the right eye and 20/25 in the left eye. There was no indication for left cataract surgery.

✓

CASE 30:

A

Brief summary of post operative surgical care provided by optometric practitioner resulting in misdiagnosis and protracted therapy.

D.B.

A 54 year old white male had cataract extraction and intraocular lens implant. In the immediate postoperative period he developed a redeye and headache and was evaluated by the optometrist who was providing postoperative care. The diagnosis of migraine was made and the patient was treated with pain medication without benefit. Topical medications were prescribed without benefit. With progressive symptoms he was referred to a neurologist and had extensive testing including expensive CAT scan testing without establishing a diagnosis. Subsequently he was referred to an academic medical center neuroophthalmologist who diagnosed scleritis and began anti-inflammatory therapy while also obtaining further consultation that led to diagnostic biopsy which established the diagnosis as an infection due to a fungus. Antifungal medication was successful but required three months of therapy.

CASE 31:

B

PATIENT: [redacted]
AGE: 76 [redacted]
SEX: FEMALE
RACE: CAUCASAN
DOB: 3/3/12

Patient told she needed a cataract operation and the fact that she is doing well did not mean she did not need a cataract operation and that Dr. had told her that the cataract needed to come out because it was too grainy.
VISUAL ACUITY; OD: 20/40-1 OS: 20/40-1

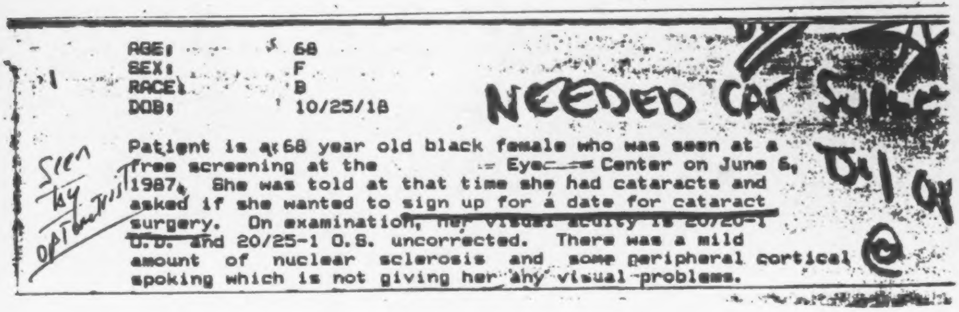
✓

NEEDED CAT.

TOC

CASE 32:

A



AGE: 68
SEX: F
RACE: B
DOB: 10/25/18

NEEDED CAT SURG

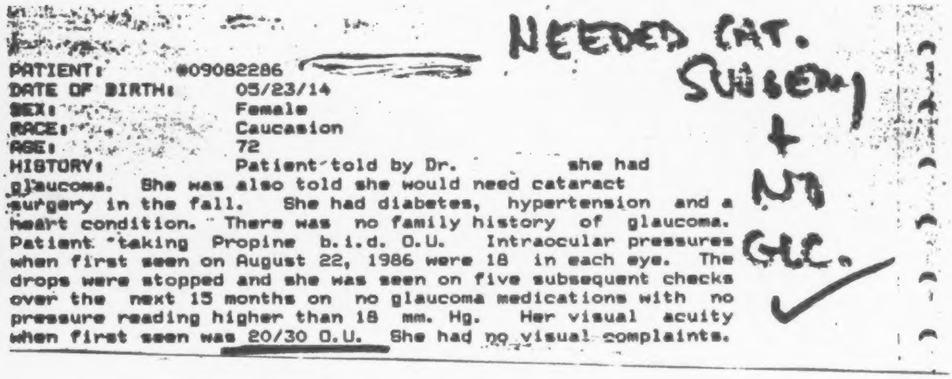
Patient is a 68 year old black female who was seen at a free screening at the Eye Center on June 6, 1987. She was told at that time she had cataracts and asked if she wanted to sign up for a date for cataract surgery. On examination, her visual acuity is 20/20-1 O.D. and 20/25-1 O.S. uncorrected. There was a mild amount of nuclear sclerosis and some peripheral cortical spoking which is not giving her any visual problems.

Sign by optometrist

@

CASE 33:

B

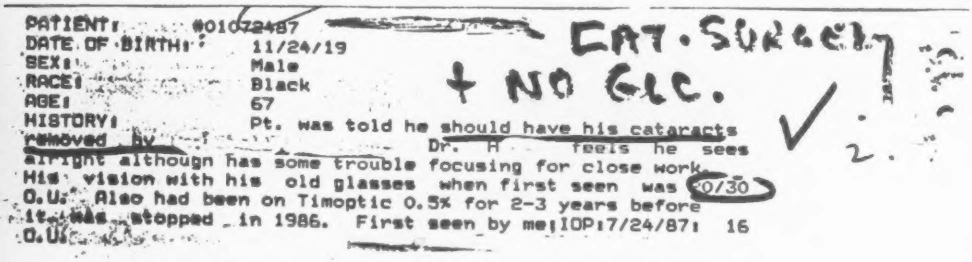


PATIENT: #09082286 [redacted]
DATE OF BIRTH: 05/23/14
SEX: Female
RACE: Caucasion
AGE: 72
HISTORY: Patient told by Dr. she had glaucoma. She was also told she would need cataract surgery in the fall. She had diabetes, hypertension and a heart condition. There was no family history of glaucoma. Patient taking Propine b.i.d. O.U. Intraocular pressures when first seen on August 22, 1986 were 18 in each eye. The drops were stopped and she was seen on five subsequent checks over the next 15 months on no glaucoma medications with no pressure reading higher than 18 mm. Hg. Her visual acuity when first seen was 20/30 O.U. She had no visual complaints.

NEEDED CAT. SURGERY + NO GLC. ✓

CASE 34:

B

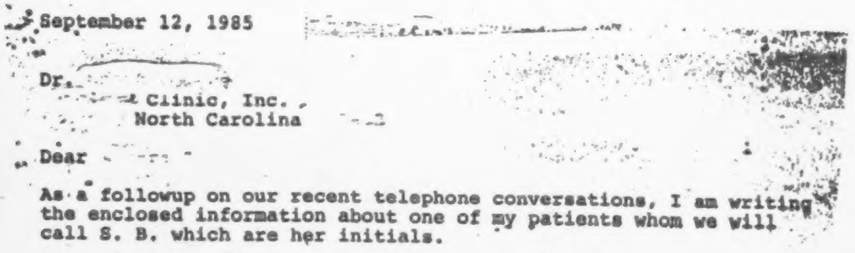


PATIENT: #01072487 [redacted]
DATE OF BIRTH: 11/24/19
SEX: Male
RACE: Black
AGE: 67
HISTORY: Pt. was told he should have his cataracts removed by Dr. H feels he sees alright althougn has some trouble focusing for close work. His vision with his old glasses when first seen was 20/30 O.U. Also had been on Timoptic 0.5% for 2-3 years before it was stopped in 1986. First seen by me; IOP: 7/24/87: 16 O.U.

CAT. SURGERY + NO GLC. ✓ 2.

CASE 35:

A



September 12, 1985

Dr.
Clinic, Inc.
North Carolina

Dear

As a followup on our recent telephone conversations, I am writing the enclosed information about one of my patients whom we will call S. B. which are her initials.

On 9-10-85, Ms. S. B., age 84, came to me because she was upset and felt bad and wanted a physical. She came because of hayfever symptoms with slight wheezing but during the course of the examination she asked me if I could check her to see if she had cataracts and I did and told her that she had early cataracts and then I inquired as to why she was asking and why she seemed to be upset. This lady, who has been our friend for over 20 years and has been a friend of my office secretary all of my secretary's life, then explained to us that she had been to Dr. for evaluation of her eyes, that her vision was deteriorating a little and that Dr. as she stated, acted strange, did not finish his examination but told her that she had to have immediate surgery to preserve her vision and that he was making arrangements for her to go to for this surgery. She was somewhat intimidated by this and expressed a desire to stay in and at that time stated that he told her that no one in could do this kind of surgery. I explained to her that there were four physicians in who do this kind of work reputably and correctly and at that time she pulled out a two sheet handwritten note, a copy of which is enclosed, which in effect gave her instructions for being at Dr. 's office on a given morning for transportation by car to to be operated on. The note further stated that a motel room had been reserved for her to stay after the surgery and overnight and the following day she would be brought back to

The patient was unaware of the name of the surgeon who would do the operation or at least she could not remember. She was quite upset about having to go out of town to have this work done and to see people that she does not know.

I explained to her that there are physicians in who do this kind of evaluation and surgery routinely and do it correctly and properly and she immediately requested that we get her an appointment at which time we called Dr. and he agreed to see her on the same day.

Since we did not know which surgeon she was supposed to go to in [redacted] I had my office secretary, to call Dr. office at which time she talked to and told her that takes care of all the arrangements and that Ms. S. B. was supposed to go see Dr. [redacted] on 9-24-85.

Please see the enclosed copy of the instructions that our patient allowed us to see and copy.

If you need any further specific information about this case, then I shall be glad to give you anything that I have.

Respectfully,

[redacted]

[redacted] M. D.

[redacted]

CC: Dr.

Enclosure

[redacted] September 11, 1985

[redacted] M.D.
Clinic
Route . Box
[redacted] NC

RE: [redacted]
M.R. #16 81 27

Dear [redacted]

The above 85 year old white female was seen 9/10/85. As you are aware, she had been told that she has cataracts and surgery is necessary and in fact, arrangements were made for patient to be picked up in and taken to to have surgery done by an unknown to me eye surgeon whom the patient has not seen. The ~~appointment~~ was to have the surgery approximately 2 hours after arriving in . The patient does not know which eye is to have surgery. She does not desire surgery and wants it only as she quotes, "have to have it".

External examination revealed pupillary reaction and extraocular muscle and lid function to be normal. The interocular pressure is 7 mm. of mercury bilaterally. Visual acuity of right eye 20/200, corrects to 20/80 with a minus 2.50 sphere. Left eye vision 20/100, corrects to 20/80 with a minus 2.25 sphere. Pupils dilated and revealed normal cornea, anterior chamber. There is nucleosclerosis. The vitreous is clear. The discs appear to be normal. There is a dry type senile macular degeneration bilaterally. It is my opinion that the cataract changes probably contribute at the most 50% of her visual deficit.

After my explaining the situation to the patient she certainly desired no surgery. No surgery was scheduled. I took the opportunity to have Dr. , a retinal specialist, to see the patient. He concurred with the above findings and felt that there is no treatment available at this time for the macula degeneration and in absence of patient's desire for surgery for the cataract, he would recommend no surgery at this time.

Thank you for allowing me to see her.

Sincerely yours,

[redacted] M.D.

[redacted]

Tuesday Sept. 24

Be at Dr. [redacted] 8 AM

On Monday night
Do not eat or drink
After 12 midnight

Lady will meet you at
Dr. ______ at 8 AM
And drive you to
______

Sugery at 11 AM Tuesday
______

She will take you to the
motel room later in the da
______

The room is reserved for yo

A nurse or sitter will
spend the night with you
and get your supper Tues
And your breakfast Wed.
______

Driver will pick you up
at motel Wed. Morning to
ome to
______

I will pick you up at
7:AM at Dr.
on Wed. Morning.

CASE 36: D

FROM: - One eyed patient who had vision of 20/25. Patient was told that he did not need surgery. One month later he underwent cataract surgery with implant in the same eye, by Eye Clinic. He then underwent enucleation of a blind eye which was not bothering the patient. He came back to Dr. after experiencing an episode of extrusion of the orbital implant after enucleation in that eye.

CASE 37: A

FROM: - told by an optometrist that he had glaucoma and was referred to for laser treatment. The patient came to Dr. for a second opinion and was found to be only on Timoptic eye drops. With the addition of another set of eye drops the pressure was under good control.

CASE 38: A

Case Report

Chart# 030-05

The patient is a 60 year old white male who presented on July 6, 1987 having been followed by a optometrist in a surrounding community. He had been found to have unilateral glaucoma of the left eye some 3 months prior to that examination. He had been using Betagan and Propine and his pressure was 16 in the right eye and 24 in the left eye before the patient presented for his examination. Since his optometrist was unable to reduce his pressure below 20, it had been recommended that he go to a outlying community for Argon laser trabecularplasty. However the patient presented to me for a second opinion.

The patient was found to have 20/25 vision in the right eye and 20/30 in the left eye with his current glasses. The left pupil was alittle larger than the right. His funduscopic examination showed the right eye to have normal appearing disc while the left eye showed vertical enlongation and nerve fiber layer drop out consistent with glaucoma. His intraocular pressures measured 17 and 21. Gonioscopy revealed Grade IV open angles.

I felt that the patient had unilateral open angle glaucoma with borderline control. He was started on Pilocarpine 1% qid and his pressures remained in high normal range through out the ensuing year. There had been an inadequate trial of medical therapy before laser was recommened. His visual field test have remained unchanged during this period of time. We have been able to avoid the use of Argon laser trabecularplasty with appropriate and adequate antiglaucoma therapy.

CASE 39:

C

Case Report

Chart# 044 19

A 30 year old white male who was seen by a local optometrist in either September or October of 1987 was told that he had a cataract in his right eye that needed to be removed. He had noted black specs infront of his vision and he had no discomfort associated with it. He noted that the vision was deteriorating. He was unable to see the cash register and he had to quit his job as a cashier because of the mistakes he had been making. His vision was found to be counting fingers in the right eye and 20/20 in the left eye. His funduscopic examination showed a heavy cellular response within the vitreous and the retina was barely seen in this eye. His left eye was normal. His slit lamp exam showed mutton fat KP with 1+ cell and flare. The anterior vitreous had a 3+ cell present. There was alot of debris within the vitreous cavity. His intraocular pressures were normal.

I felt that the patient had a intermediate uveitis. He was treated with subtenons steriods as well as topical steriods and cycloplegics. His general medical work up revealed evidence for sarcoidosis and a general medical evaluation through the offices of Vocational Rehabilitation Services revealed pulmonary sarcoidosis. The patient required several subtenons injections of the steriods and over a period of about 8 weeks the patients vision was improved to 20/30.

First and foremost this patient did not have a cataract and secondly there was no need for surgery. He required medical treatment of the uveitis.

CASE 40:

B

CASE REPORT

Mrs. B. D. was seen in December of 1980 by Dr. K. At that time, her visual acuity was 20/20 in the right eye and 20/200 in the left eye. She was found to have an old chorioretinal scar in the left previously diagnosed as toxoplasmosis and treated at Bascom Palmer Eye Institute in Miami. She was seen regularly over the next seven to eight years. As an example, she was seen in August 1985 at which time her visual acuity was again corrected to 20/20 in the right eye and 20/200 in the left. She subsequently developed early nuclear sclerosis in both eyes and was seen by Dr. M.C. at Eye Center in consultation. It was felt by both Dr. C. and Dr. K. that it was premature for her to have cataract surgery. It was also noted by atleast three independent observers that her anterior chamber was deep. In October of 1987, her visual acuity was best corrected to 20/30 plus or minus in the right eye and 20/200 in the left. She was last seen most recently by Dr. K. on April 11, 1988 at which time her visual acuity was best corrected to 20/80 in the right eye and 20/200 in the left. Her applanation tensions at that time were 20 and 18 and as well her anterior chamber was noted to be deep. It was noted that the cataract had advanced and it was recommended to the patient that she have cataract surgery in conjunction with a lens implant in the right eye. The next communication with the patient was in May of 1988. The patient requested that Dr. K. provide post-operative care. She stated that she had been seen in and had been told that she needed cataract surgery but, as well, had glaucoma and needed surgery urgently. She subsequently had surgery the next day for both cataract and glaucoma in the right eye and, as well, glaucoma in the left.

This case represents a situation in which a patient legitimately was in need of cataract surgery but was diagnosed as having glaucoma of such an acute nature that almost immediate surgery was indicated. With a past history of almost eight years it is very doubtful that the patient had acute glaucoma. It was noted during their exam in that the angles were open and the applanation tensions were normal, but urgent treatment was recommended. The urgency of any treatment is in question.

CASE 41: C

CASE 2) An 80-year-old black male with bilateral cataracts. Patient was told that he had to have emergency surgery as soon as possible. The patient came to see me for a second opinion. I concurred with the diagnosis of cataracts; however, I could find no reason for an emergency operation. The patient's pressures were normal, and there were no signs of any inflammation in the eye that would be consistent with a rare form of cataract extraction. I advised the patient that it was an elective procedure, and he could have it done at any time he so desired. The patient elected to stay under my care and underwent uncomplicated cataract surgery at our local hospital.

CASE 42: A

CASE 3) A 75-year-old white female who was instructed by her ~~ophthalmologist~~ optometrist that she had to drive approximately 100 miles to a facility that could perform her special cataract operation. She was told that there was nobody in the immediate area that could perform this type of surgery, and it was necessary for her to travel to this location. Patient went to this location and underwent cataract surgery without complications; however, a few weeks after the operation, she fell causing injury to the operative eye. Patient was unable to return to this facility becuase of the distance involved, and the local referring optometrist was unable to attend to this patient. The patient went to her family doctor who referred the patient to me for medical care; which was delivered. The patient responded well to medical therapy without any further complications. What would have happened to this patient had she fallen more seriously causing rupture of her surgical wound requiring immediate and urgent surgical care?

CASE 43: A

PATIENT PUT TO UNNECESSARY TROUBLE..

This is a two year old child who went to an optometrist because he had a chalazion-a type of sty on the upper lid. The optometrist knew that the treatment for this was incision and drainage. He told the patient's grandmother that she would have to take him to a town out of county to have this done as nobody in Shelby did this kind of work.

This of course is the kind of thing that any ophthalmologist does regularily and does it in his office on adults. A child has to be done at the hospital under general anesthesia because it does cause a little bit of pain in children. Fortunately, the grandmother thought better of this disposition and checked out the hospital and found out she could have it done here.

One can only guess how much trouble patients are put through by optometrists by referring them to distant places. If one were to extend this type of philosophy throughout medicine, the local general surgeon would not even do hernias! They would be done elsewhere also.

CASE 44: C

FAILURE TO DELIVER REQUESTED OPTOMETIC REFERRAL CARE.

This patient I never actually saw. I got a call from an optometrist's office in a city of my own county. He wanted to refer a patient for cataract surgery and I said fine, "thank you". Well, the patient never came at the appointed time. We learned from the optometrist that it was his custom to send the patient for cataract surgery and that this should be performed immediately. I wrote this optometrist a letter and explained that since I was the operating surgeon I preferred to see the patient in consultation and decide for myself whether or not surgery was required. I found the patients like that kind of contact and care.

CASE 45: A

UNNECESSARY CATARACT SURGERY.

This is an 80 year old patient-a patient of mine. I saw him years ago and he had small cataracts. In the meantime he went to an optometrist who sent him to an ophthalmologist out of the county. He operated one eye and that was quite sucessful. I have no idea what the pre-operative vision was. In any event, he was sent to me for a second opinion in regard to his other eye.

This man had 20/30 in his other eye and had no real obvious disability. He did know that the vision was reduced and that he could see better out of his operated eye. He was scheduled for surgery and seemed quite happy to go along with it. I had my office manager quickly check his vision and she came up with 20/30 as I had. I pointed out to him that his vision was pretty good, and that it was obvious he wanted to proceed with surgery. I approved it tongue-in-cheek.

I find it interesting that but a few years ago in the United States approximately 5 or 600 thousand cataract surgeries were performed yearly. This number has nearly tripled in just a few years. I think we can understand why-it seems that nowadays the indication for cataract surgery is its presense. It doesn't matter if the patient has any real disability.

CASE 46: A

OPTOMETRISTS UNABLE TO TAKE CARE OF POST OPERATIVE PROBLEM.

This is a 74 year old man who could barely walk who lives in [redacted]-my town. I had seen him years ago with minor cataracts. His caregiver, a son, lives in [redacted], well over a 100 miles away.

I was called at 10:00 one night during a dinner party to come see this patient. I was called by a general practitioner as he thought the patient had glaucoma. It seemed that he had been operated several months previously in [redacted] by a fly-in ophthalmologist. He was seen once after surgery by an ophthalmologist [redacted]-a different one then the operating surgeon- and turned over to the local optometrist for follow up care. The optometrist had sent the man to [redacted] originally for the surgery.

He developed some pain in his eye the middle of the week and on Friday was sent by the optometrist to a local general practitioner who sent the patient immediately back to [redacted] where he was seen by a medical ophthalmologist. His medical ophthalmologist did not know the patient and had no records other than operative note to go by. The operative note indicated problems at the time of surgery.

In any event, he gave this man Atropine to dilate the pupil and a steroid/antibiotic drop to reduce inflammation. The next day, a Saturday, the patient was seen by the original GP's son who worked in a partnership and this is how I came into the case.

I left the dinner party around 10:00 and saw this patient in the office. His pressure was 66 and he was vomiting. He had a steamy cornea and I could not tell much about the anterior chamber of his eye. Things did not look well and I said he needed to be in the hospital immediately. His son from [redacted] was with him. His son agreed. This man refused to go into the hospital and wanted to go see the fly-in ophthalmologist at his home base-a town well over 100 miles from [redacted]

I got the pressure down to around 30 by using strong intravenous medications and sent him on his way. I have no idea how this turned out.

Here is an elderly patient living in my community who could hardly walk who could have had his surgery done here. There might well have been complications with it at the time of surgery. He might have had long term complications. The point is, these could have been easily taken care of here with little trouble to the caregiver assuming some local transportation perhaps from a chuch could have been arranged.

Even if I wanted to fee split or kick-back to local optometrist I really could not do that. The reason is, the local patient would assume that his care would be given by the local operating surgeon if he had it done locally. Therefore, I am effectively cut out of even contemplating this unethical practice-I suppose I could make a liaison with an optometrist 40 or 50 miles away-but not in my own community.

I think the biggest point to remember about this elderly gentleman operated by the fly-in surgeon is that late complications are going to occur. They need to be recognized and I doubt that many optometrists can recognize all of them.

They then need to be treated and optometrists simply cannot treat many of these severe late complications.

For Buckaneer ophthalmologists to state that the complications are rare or unusual misses the point. They are not God nor am I Marcus Welby.

CASE 47: A

INAPPROPRIATE CATARACT SURGERY IN THE DIABETIC PATIENT.

A 55 year old lady came for second opinion. Her vision was 20/40 in each eye with ease and she had no real visual disability. She was scheduled for surgery by an ophthalmologist in a small town not far from She had significant diabetic retinopathy that was easily seen through her cataract. I told her she did not need cataract surgery but needed her retina examined and probably treated with the laser.

She went home, called the other ophthalmologist who immediately called me on the phone and castigated me for my opinion. He said quite clearly that "now I cannot deliver the surgery for the optometrist". He later wrote a two page letter raking me over the coals.

The patient obtained a third opinion from a retinal specialist in who agreed that laser treatment was necessary and perhaps cataract surgery would never need to be accomplished. I received a hand-written letter of apology from this over active surgeon who could not deliver for the optometrist.

The ophthalmologist was afraid that if he could not deliver the goods the optometrist would not send him any more patients.

Above and beyond that, had the optometrist been properly educated in the pre-operative diagnosis of when a patient should have surgery, he never would have sent the patient to start with. He would have known she needed retinal evaluation and possibly laser treatment and sent the patient for that.

Needless to say, the ophthalmologist should have known better-we always want to treat the diabetic retinopathy if it needs treatment prior to doing cataract surgery as cataract surgery can make diabetic retinopathy worse.

CASE 48: A

Mrs. S. is an 84 year old, old patient of mine seen many times slowly developing cataracts. Eventually vision dropped to around 20/70 and glasses could not be altered to improve her vision and I recommended cataract surgery. The next time I saw her was in the office for post-operative care. She had been operated on at a cataract mill elsewhere in North Carolina - both eyes. The result was satisfactory. She did have some double vision but there were no arrangements made with me or anybody else for that matter for post-operative care. Because I treat many members of her family I put my tail between my legs and agreed to take her on. I asked her why she went out of town for surgery and she said it was because she saw an ad.

CASE 49:

A

FAILURE TO PROPERLY ARRANGE FOLLOW-UP CARE.

John was 50 and had poor vision in his right eye all of his life from a traumatic cataract due to an injury at age 3. His vision was light perception. Vision on the left was 20/20. I had seen him for years and advised against cataract surgery.

Eventually, he saw a local optometrist who sent the man out of state for cataract surgery. He had this performed, there were problems at the time of surgery with loss of vitreous. He had an anterior chamber lens implant and was sent back to me for post-operative care. The patient came around the office, had no improvement of vision, and had an eye full of blood. Since this patient had abandoned me and since no arrangements were made for follow-up care and because of the complications, I felt that he should go back to the operating ophthalmologist to have this situation treated.

CASE 50:

A

Case Summary

O.M. is a 71 year old lady who was originally seen in this office on 12/08/80 with the visual acuity of 20/80 OD, 20/400 OS. She was noted to have a vitreous hemorrhage and was referred to her local physician for evaluation. She was found to have diabetes and begun on Insulin. On follow-up evaluation visual acuity had decreased to light perception and she was referred to Dr. [redacted] at the [redacted] Eye Center for evaluation. Ultrasound showed no evidence of retinal detachment and she was followed through July 28, 1981 at that institution without significant improvement. She was then lost to follow-up.

On 11/08/87, Dr. [redacted] was called by the [redacted] Hospital. He was requested to see the patient for severe pain in the right eye.

The patient had originally been at the hospital on 11/07/87 and admitted for nausea and vomiting. On 11/08/88 the general practitioner called the local optometrist who had been caring for Mrs. M. in the post-operative period. The order sheet shows that Tetracaine eye drops were ordered by verbal order and then later a second order for Diamox 250 mg. now and again in 30 minutes and another order for 2% Pilocarpine every two hours was given. In addition, the optometrist stated that if the patient was released, he would see the patient in his own office in the morning.

Because of the continued severe pain, Dr. [redacted] was contacted who cancelled the above orders. The patient was seen in the hospital and taken to the office where a pressure of 60 by applanation was noted. The patient's visual acuity was 20/60 OD, hand motions OS. Slit lamp exam showed there was marked corneal edema. The anterior chamber was deep but there was marked iritis with some iris bombe and a complete membrane covering the intraocular lens. Vigorous dilatation was carried out. Several small breaks in the pupillary membrane were effected and the pressure dropped to 32 in the left eye. The patient then returned to the hospital where she continue her intravenous fluids. The miotic drops, as well as Pred Forte every four hours were continued. She was also given 500 mg. of IV Diamox intravenously.

On the next morning the pressure had fallen to 10 and her anterior chamber reaction was considerably improved. She was therefore continued on her Pred Forte every two hours, Cyclogyl tid and she then returned on 11/10/87. At this time she showed further clearing of the anterior chamber and the cornea with a pressure of 10.

She was then followed with gradual resolution of the remainder of the iritis and the pupillary membrane. When last evaluated on 04/06/88 she had a visual acuity of 20/200 OD, 20/400 OS. Tensions by applanation were 17 OD, 15 OS. The slit lamp exam showed the cornea, anterior chamber and iris were clear. The lens was in good position. The funduscopic examination through a dilated pupil on the right showed a macula scar with a hole in the macula.

This case is presented to demonstrate the inadequacy of care suggested by the optometrist involved. Appropriate medical attention was obtained, the proper therapy was given, and the patient has done reasonably well.

CASE 51: A

ZM, an 80 year old retired school teacher, had been followed since 1949 at a local ophthalmologists office. Her vision was found to be decreased in 1984 to about the level of 20/70, and later that same year to about 20/100. The surgeon caring for her informed her that her primary problem was macular degeneration. Altho she was also developing cataracts, they were about the same in both eyes, and her surgeon felt that removing them was not likely to improve her vision much and could even cause more damage. Her other eye remained correctable to 20/25 with spectacles at this time, and had a similar cataract.

She had heard of a cataract specialists in another town, and went to get his opinion. Her eye exam was performed by an optometrist in the employment of the surgeon, who found her best corrected vision to be 20/200 in the right eye and 20/80 in the left, diagnosed cataract as her problem, and graded the cataracts in both eyes as exactly the same with respect to 4 different catagories of lens changes. Neither the operating surgeon nor any other physician saw the patient pre-operatively. There was never any recovery of vision following the surgery, and within one week the patient had obviously undergone a hemorrhage in the macula (as her previous ophthalmologist had worried may happen). Today her best corrected vision is the ability to count fingers at 3 feet.

Incidentally, there was a month between the time of the initial eye exam and the surgery. No attempt was made to recover her records from the practice that had followed her for over 30 years. Also her pre-operative physical exam was apparently performed by an optometrist, and no operative permit was ever signed.

She returned to her previous ophthalmologists office in 1985, where her problem was explained (for the first time,according to her). The vision in the left eye (never operated) was correctable to 20/30-2.

CASE 52: A

GG presented to her local eye surgeon for a routine examination, where she was found to have perfect corrected vision, pressures in the eye of 14, and no cataract or other abnormality. Her angles were slightly narrowed as noted on the chart, and there was some mild asymmetry in the cupping of her optic discs, but the cups were estimated at 30-40% in one eye, and 20% in the other. No changes were seen under the anterior lens capsule to suggest episodes of glaucomatous attacks, and a careful,specific history was taken that was also negative. She was told of the exact nature of the above findings, and her pupils were dilated, after which the pressure remained th same. Her angles were still open.

The patient was warned about the possible signs of a glaucoma attack, and told that other tests were needed (such as visual fields), but that since she was in a hurry that day, these tests could easily be put off for several weeks. In addition, it was suggested that she come to the office at a different time of the day, to recheck her pressures.

Her mother had been referred 130 miles away for cataract surgery by her local optometrist, and the patient accompanied her for an examination after her surgery. While sitting in the office, she was approached by the eye surgeon that had operated on her mother, and told that her pressures in each eye were extremely high. The patient later denied that she was in any pain, but that her eyes were still a bit red from the drops administered in her own doctor's office. She then underwent emergency laser surgery for glaucoma in both eyes at the same time. In addition, she was told that her own doctor had done a poor job of caring for her appropriately (although no calls were made to determine the past history or examination findings). She was also told then and later that she may well have gone blind if she had not received such rapid treatment.

She was seen later by her local eye surgeon who was unaware of her recent circumstances. Her pressures were normal, and optic nerves unchanged. She began to cry when asked when she had received surgery (obvious from the examination). She related the above story (and has subsequently signed a written deposition), and told [illegible] that she did not want to return to the other surgeons again. She was afraid her own local surgeon would not want to care for her,and was assured by him that it would in no way change her care.

CASE 53: A

EH had been under the care of her local eye surgeon since 1976, with many refractions that yielded excellent 20/20 acuity in both eyes. She developed psychological problems that resulted in referrals to two different academic centers nearby. In both centers she was carefully examined by faculty from the ophthalmology departments, and found to have a subjective decrease in vision without any explanation based on examination of the eyes. Her visual field tests clearly demonstrated hysterical (psychogenic) field loss and she was carefully counselled concerning the need for psychiatric evaluation and care. Her local eye surgeon was requested by the patient to perform cataract surgery, and since he was not convinced that the surgery was indicated, he agreed to do it after yet another examination at a medical school nearby. The physician that examined her was very concerned that any surgical out-come would be compromised by her poor self image and mis-perceptions of her vision. In addition he could refract her to 20/25 with encouragement. Her medical history was further complicated by a well documented allergic response to polymer plastic, and the referral physician suggested that no intra-ocular implant be placed in the eye until her skin sensitivity to the exact polymer (and other chemical agents bound in the polymer) was independently evaluated by a dermatologist.

This patient was asked to acquire a second opinion from an independent eye surgeon in the immediate area (not financially connected with her own private eye surgeon). She found an optometrist closer to home and, without realizing the difference in background and training, requested a second surgical opinion. He referred her to a cataract surgeon with which he had referral arrangements, and she was scheduled for surgery.

Her personal eye surgeon called to ask why she had not kept her appointment with the second opinion surgeon, and was told of the above arrangement. He then immediately called the cataract surgeon and personally told him of the very complicated past history of the patient, but was informed that the lady had already undergone surgery, with implantation of an intraocular lens, and no knowledge of her past psychological/medical problems. This patient has never been seen by her local ophthalmologist again, so her outcome is not known.

CASE 54:

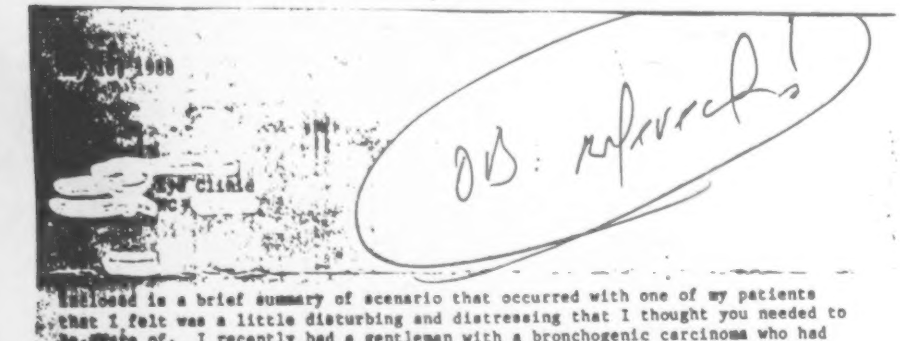
D

JP, a practicing physician, was cared for by local ophthalmologists with moderate to high myopia for many years. When he developed a cataract in his left eye, he went out-of-town to a high volume cataract surgeon for his surgery. Vision in the fellow eye was 20/20.

Two years later he was found to have a cloudy capsule behind his implant with 20/400 vision, and a very large superior retinal hole with surrounding retinal detachment. This was repaired after two separate laser procedures, and the vision was returned to 20/20. He stated that he ignored the loss of vision and other symptoms because no one at the high-volume surgeons office had ever informed him of increased risks of retinal holes and detachments following cataract surgery to persons with high myopia. He therefore did not seek treatment until his vision was so compromised that he could no longer practice medicine. His retinal hole has required retreatment, but the eye still remains capable of 20/20 vision. He has decided to delay a similar cataract operation in the fellow eye with vision 20/50 because he now understands the risks and is not willing to again take them.

/

CASE ~~54~~: 55



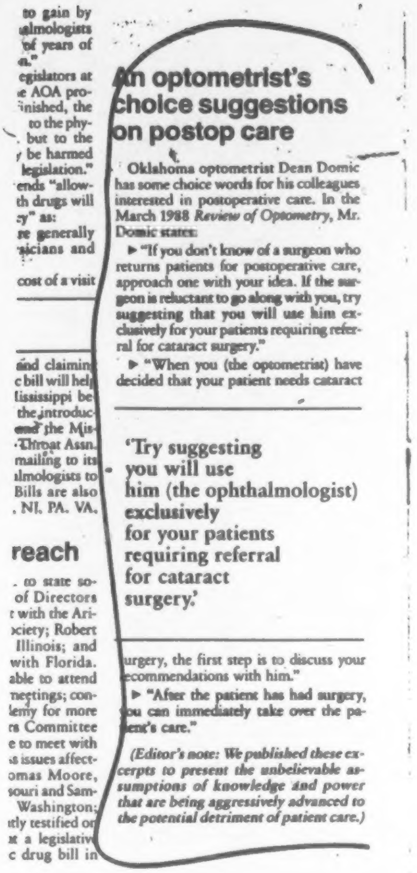
[illegible] 1988

Eye Clinic
NC

OD: referrals!

Enclosed is a brief summary of scenario that occurred with one of my patients that I felt was a little disturbing and distressing that I thought you needed to be aware of. I recently had a gentleman with a bronchogenic carcinoma who had received radiation therapy for his tumor and was in a slowly progressive phase with his tumor. He had minimal pulmonary reserve and our goal was simply symptomatic control and comfort realizing that his time was very short in terms of just a few months and to do what we could to allow quality of survival, pain control and death with dignity when that time came. Recently unbeknownst to myself he had cataract surgery performed in a nearby town which was disturbing in its own right considering his overall prognosis and his medical problems, he then went back to see them on the date I admitted him to the hospital, he was told that he was sick and just needed to go see his family doctor and he drove back 33 miles to see us and has been admitted to the hospital and has been in the hospital now over 2 weeks as we are trying to get his pulmonary status back up where he can hopefully go home. He will now be on oxygen permanently for the remainder of his life. I don't think that the complications that he is having now had anything whatsoever to do with his surgery, it's just that he was very near death to start with and he now has a new lens in his eye, he can't see any better than he could before, at least not according to the patient, but did [illegible] in having a cataract removed. The patient was generally an unsophisticated individual, lower socioeconomic status, probably is not able to read initially let alone with his cataract and in a way from my point of view anyway has been physically assaulted by having a lens put in for he had one put in when I don't think he really understood what it was for. The other disturbing point is that if his physician knew that he had lung cancer that was progressive and expected to be fatal in the not too distant future I am not sure why the lens was put in and if he didn't know it, I wonder why he didn't find out what was going on with this patient. In either approach, I find the actions of the ophthalmologist to be unethical or to border on being unethical and I plan on discussing it with that individual in the not too distant future. I will also be sending a copy of this to the NC Medical Review Board and if they wish to know his name and the patient's name, I will be glad to furnish that to them. I hope with time, that inappropriate surgery will be a phenomenon of the

RELATED MATERIALS



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An optometrist's choice suggestions on postop care

Oklahoma optometrist Dean Domic has some choice words for his colleagues interested in postoperative care. In the March 1988 *Review of Optometry*, Mr. Domic states:

▶ "If you don't know of a surgeon who returns patients for postoperative care, approach one with your idea. If the surgeon is reluctant to go along with you, try suggesting that you will use him exclusively for your patients requiring referral for cataract surgery."

▶ "When you (the optometrist) have decided that your patient needs cataract surgery, the first step is to discuss your recommendations with him."

▶ "After the patient has had surgery, you can immediately take over the patient's care."

(Editor's note: We published these excerpts to present the unbelievable assumptions of knowledge and power that are being aggressively advanced to the potential detriment of patient care.)

> 'Try suggesting you will use him (the ophthalmologist) exclusively for your patients requiring referral for cataract surgery.'

December 18, 1984

is pleased to introduce an innovative program which will significantly benefit you and your cataract patients.

As you may know, we at strive to provide the finest surgical eye care in a state-of-the-art facility. And, because our ambulatory surgery center is licensed by the state and Medicare-certified, we are able to provide our medical services at minimal cost to the patient.

Our new program affirms our dedication to providing the highest quality eye care to the elderly citizens o the Carolinas. It is designed to ensure that your patients receive the optimal care available to them, and enables us to follow your patient through their entire treatment program.

We are offering to work closely with optometrists, such as yourself, to diagnose and treat cataract surgery patients. We guarantee our best effort to return your patient to your practice following surgery, and we will compensate you $100.00 per case to cover the cost of the post-operative care you will be providing. To selected optometrists that meet certain referral criteria, we are also providing, free of charge, a video cassette recorder and a custom video-tape program designed by us to educate your patients about cataract surgery, and help them feel more at ease with the procedure. Other features of our program include:

- free continuing education seminars on post-operative cataract surgery care
- free transportation for the patient and escort, if needed
- free overnight accommodation for the patient and escort on the day of surgery

We look forward to meeting with you at your office to discuss the details of our new program. We will contact you within the week to schedule an appointment.

Sincerely

Dear Dr.

This patient had a cataract extraction with the insertion of a posterior chamber lens implant on the right eye on 6/24/83.

Today we found the vision to be 20/30 with a refraction of +1.00 -4.25 x 175°, with an intraocular pressure of 11.

I would greatly appreciate your seeing her for a final glasses correction at approximately three months postoperatively.

Thereafter, I would certainly appreciate your seeing her every six months for routine vision and pressure checks.

Enclosed please find a check in the amount of $50.00 to help cover the cost of this visit, which we would normally do.

If there are any questions, or any problems at all, please do not hesitate to contact me.

Thank you in advance for your help in the followup care of this very nice patient.

Sincerely,

M.D.

Enc. $50.00 check
cc:

Addendum - Vision in the left eye is 20/80 with an intraocular pressure of 15.

Dear Dr.

This patient came to see us yesterday, August 29th, for a cataract evaluation of the left eye. Following a thorough examination I informed the patient that a cataract extraction with the insertion of an intraocular lens would indeed benefit her. I performed this surgery the same day, here in the clinic, under local anesthesia.

Today, one day postoperatively, vision in the left eye is count fingers at 10 feet pinholing to 20/60. Pressure is 9.

This patient will be leaving our area shortly and I would like to ask your assistance in following her. She should be seen at one week and six weeks postoperatively for a vision and pressure check. Approximately three months from the date of surgery the patient should be ready for a final glasses correction. Thereafter I would appreciate it if you could then see Susan every six months for routine vision and pressure checks.

Enclosed please find our check in the amount of $100.00, which is the amount we allow for postoperative visits for our surgical patients.

If there are any questions, or any problems at all, please do not hesitate to contact me. Thank you for the excellent care that you gave to Susan following the surgery on her right eye. I feel quite confident that she will again receive the same outstanding treatment now for her left eye.

Sincerely,

Enc. $100.00 check
cc:

THORACIC & VASCULAR SURGERY
[illegible] DAVIS II, M.D., F.A.C.S.
ROGER Z. THURMAN, M.D., F.A.C.S.

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EXECUTIVE VICE-PRESIDENT
BENJAMIN BROCKWELL

CAROLINA CLINIC, INC.
1700 S. TARBORO STREET
WILSON, NORTH CAROLINA 27893
PHONE 291-1300

January 12, 1988

Mr. George M. Mellis
U. S. General Accounting Office
Regional Office
5705 Thurston Avenue
Virginia Beach, VA 23455

Dear George:

I have reconstructed the original letter I composed to the Medicare people in January 1986. I have located and enclosed all of the accompanying documentation for this initial cover letter. I believe it is completely self-explanatory and details the objections of organized ophthalmology vis-a-viv the unbundling of ophthalmic surgical fees. It also strongly criticizes the Health Care Financing Administration for not enforcing the fraud and abuse provisions of the Medicare Act in regards to certain "high volume" surgeons offering expensive appliances to their referring optometrists.

The second letter was written to Dr. Kenneth Michael Nelson at the Office of the Inspector General in Washington, D. C. This letter refers to the initial lengthy cover letter and encloses some of the replies from the Medicare people to myself about the original letter. I would direct your attention to document 17 which specifically alludes to the issue of offering video tape machines and television sets and states that "through subsequent discussion with Health Care Financing Administration, the offering of VCRs, etc., was discouraged, and as far as we know, was discontinued". Again, I strongly criticize the Health Care Financing Administration for not aggressively investigating these obvious fraud and abuse violations. I would also direct your attention to document 19 which is a reply from myself to Mr. Al Walsh (Administrator for Medicare in the State of N. C.) where again I allude to the fact that Medicare seems to have given preferential treatment to certain high volume ophthalmic practices of this state. These practices were given assurances that their fee splitting arrangements with optometry were acceptable to Medicare as long as the surgeons involved provided a list of the optometrists with whom they had contracted. Yet in the Medicare warning (Transmittal 84-4-my document #3), it specifically states "optometrists and other health care professionals are in the position to direct patients to particular suppliers or physicians pursuant to an arrangement and then receive payment from the physician for the referral, etc. etc." It also states "the statute proscribes payment or receipt of any remuneration that is intended to induce a referral. The opportunity to generate a fee is itself a form of remuneration. The offer or receipt of such fee opportunities is illegal if intended to induce a patient referral." As you know, this has been subsequently born out in case law in the Greber case. It seems that the physicians of N. C. were strongly warned not to engage in this type of fee splitting activity through this public transmittal, but certain high volume ophthalmologists were privately reassured that these arrangements were o.k. as long HCFA was informed with whom they had contracted. What is the difference between contracting with optometrists for these guaranteed fee generating opportunities and being involved in such opportunities "pursuant to an arrangement"? Obviously, there is a huge conflict here which must be resolved.

I simply cannot locate document 20 which is a response from Robert Striemer at the Bureau of Eligibility, Reimbursement and Coverage. I do remember the response, however, and Mr. Striemer indicated that all these arrangements had been reviewed and approved by the Inspector General's Office. I wonder if this is true.

I have also enclosed some related documentation which you may find of interest. Document 21 is a copy of an optometric referral list from one of these high volume surgery practices. Apparently, these optometrists had completed a two hour "postoperative care course" in the office of the surgeon in question and were then deemed "qualified" to assume the postoperative care of virtually any cataract patients they referred to this surgeon for cataract surgery. Of course, it is a virtual certainty that such patients will be returned to the referring optometrists with a "postoperative care fee" - a guaranteed fee generating opportunity. In addition, many of these optometrists received a video tape machine and color television set for participating in these arrangements. As you can see, this list contains over seventy optometrists and represents a tremendous volume of potential surgical patients. Virtually every ophthalmologist in the communities where these optometrists reside will not provide their optometrists with a guaranteed fee generating opportunity and are hence totally shut out of the referral picture. Document 22a is a summary concerning a N. C. State Ophthalmological Society standard of care poll which was conducted in early 1986. The purpose of the poll was to determine once and for all what the prevailing practice pattern and minimum standard of care was in N. C. for ophthalmic surgeons and their postoperative cataract surgery patients. The results have already been forwarded to the inspector general's office, and I believe you are well acquainted with the fact that 96% of the responding opthalmologists provided their cataract surgery patients with at least four hands on postoperative visits. In addition, 91% of the ophthalmologists surveyed follow their patients for eight weeks or longer. No ophthalmologist followed their postoperative cataract surgery patients for any less that five to seven weeks. I believe the standard of care speaks for itself. Document 22b is a copy of the eye care poll itself. The poll was mailed to every ophthalmologist in the State of North Carolina, and an honest attempt was made to obtain a fair and truly representative poll of the practice patterns of the ophthalmologists in the State of North Carolina.

Document 23a is a letter from one of our "high volume" surgery practices in N. C. Again, we see that video tape machines and color television sets are rather routinely offered to "participating" optometrists. Again, it must be emphasized that these expensive appliances were delivered to optometrists' offices for extended periods of time and were critical in forming these large optometric referral networks which exist intact up until the present time. I wonder how the inspector general's office would view the present day offering of expensive appliances, automobiles, ocean front condominimums, etc., etc. to referring paraprofessionals in exchange for the referral of patients. This is a very troubling issue which should be addressed. Document 23b is another letter from one of our "high volume" surgery practices in N. C. The letter mentions a "Professional Referral System, which . . . allows doctors to perform postoperative examinations for a fee." Again, we see that patient referrals are again firmly linked to guaranteed fee generating opportunties - a practice which seems to be in direct conflict with the fraud and abuse provisions of the Medicare Act.

Documents 24a, b, c, d, and e are declarations by the residency training programs in ophthalmology in the states of North Carolina and Virginia. These statements condemn postoperative management by optometry and emphasize the years of training required for ophthalmologists to learn to manage surgical patients. These statements are signed by the entire membership of the ophthalmology departments at the respective universities. these professors of ophthalmology have spent years training young men and women to become competent ophthalmologists. They attest to the fact that years of hospital based, supervised, residency style training is the minimum requirement for medical doctors to become competent to manage ophthalmic surgery patients. These statements speak for themselves.

Document 25 is a copy of an eye care poll which was conducted by the Board of Medicine of the Commonwealth of Virginia. Two hundred and ninety-five copies of this poll were mailed to every ophthalmologist in the Commonwealth of Virginia. Two hundred and twenty-seven responses were obtained for a 77% response rate. Two hundred and twenty-five out of two hundred and twenty-seven responding ophthalmologists (99%) felt that optometrists should not render any part of the postoperative care for cataract surgery patients based on a time interval relative to the date of surgery. Armed with this information, the Virginia Board of Medicine recently ruled that the postoperative care of cataract surgery patients was the practice of medicine and was to be legally performed only by licensed physicians (doctors of medicine or osteopathy) in the State of Virginia. Again, the the standard of care as borne out by statistical analysis and by decree of the Board of Medicine is firmly established in this state as well.

Document 26 is a resolution which was adopted by the N. C. Medical Society House of Delegates on May 3, 1986. This resolution strongly supports the Board of Medical Examiners of North Carolina in their position that the postoperative care of cataract surgery patients constitutes the practice of medicine. The N. C. Medical Society strongly encourages its membership to provide postoperative care in accordance with the ethics of the medical profession and to report to the Board of Medical Examiners any violations of the standard of the practice of medicine. This illustrates the strong support that organized medicine has given to ophthalmology in opposing paraprofessional intrusion into the realm of managing surgical patients.

Lastly, I am enclosing a copy of the consent order (document 27a) recently signed between the Board of Medical Examiners of the State of North Carolina and an area "high volume" surgeon. This consent order speaks for itself as the physician in question admits to having engaged in unprofessional conduct and delivering care which does not meet professionally recognized standards. This surgeon routinely operated on patients that he neither examined preoperatively nor saw at any time in the postoperative recovery period. The physician was strongly reprimanded for such unprofessional conduct and was forced to adhere to a higher standard of care (one hands-on preoperative examination and at least two hands on postoperative examinations) if he was to continue to practice medicine in North Carolina. The Board of Medicine will continue to monitor this physician's practice to see that he complies with requirements of the order, and the physician agrees to open his records to agents of the Board at any reasonable time for inspection to assess compliance with requirements of this order. This consent order illustrates the extreme burden placed on State Boards of Medicine in enforcing ethical and professional standards when Medicare routinely decides to elevate paraprofessionals to the status of physicians and allows them to be reimbursed for professional services which should be left to doctors of medicine. Incidentally, this lengthy hearing was both time consuming and expensive for the State of North Carolina. I have also attached an editorial (document 27b) from the Bulletin of the American College of Surgeons (September, 1987) which is written by a past president of the American College of Surgeons. This individual very eloquently points out that "continuous care provided by the operating surgeon is superior to that provided by individuals who have lesser experience and training". He further states that modern specialists do not need to resort for itinerant surgery as preoperative and postoperative care can be administered by the surgeon in both rural and urban settings. He concluded that "convenience" and "quality" need not be mutually exclusive.

Finally, I want to point out to you that the two individuals who were initially mailed copies of these original cover letters (C. McClain Haddow, Henry Desmarais) are no longer with the Health Care Financing Administration. Indeed, one of these individuals is now in a Federal Penitentiary having been convicted of bribe taking and conflict of interest charges. The point being that Medicare sent the original kick-back warning (Medicare Transmittal 84-4-my document #3) to all licensed physicians in N. C. and strongly encouraged them to report wrongdoing to their office. Good faith complaints were made by myself and other physicians in the State of N. C., but these complaints were not handled in good faith. Not surprisingly, one of the individuals charged with administering and enforcing the provisions of the Medicare Act has been convicted of conflict of interest and bribe taking, and it is not surprising that he failed to investigate this matter in good faith.

I hope this information is helpful to you. I apologize for not being able to locate the letter from Robert Streimer, but it was of minor importance, and I have summarized its content in the accompanying letters. If there is any further information I can provide you which you might find useful, please do not hesitate to call me.

I look forward to hearing from you soon. With best personal regards, I am,

Sincerely yours,

Scott P. Bowers, M. D.

SPB/btb
Enclosure

GENERAL VASCULAR SURGERY
H. PARKE DAVIS II, M.D., F.A.C.S.
ROGER Z. THURMAN, M.D., F.A.C.S.

OBSTETRICS - GYNECOLOGY
INFERTILITY - ENDOCRINOLOGY
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JAMES R. BUSCH, M.D., F.A.A.P.

GASTROENTEROLOGY
JERRY C. WOODARD, M.D., F.A.C.P.

UROLOGY
THOMAS L. GRIFFIN, M.D., F.A.C.S.

CARDIOLOGY
J. ALLEN WHITAKER, M.D., F.A.C.P., F.A.C.C.

NEUROLOGY
HAROLD A. LADWIG, M.D.

INTERNAL MEDICINE
JONATHON C. DEWALD, M.D.

INTERNAL MEDICINE - CARDIOLOGY
WILLIAM B. YOUNG, M.D.
JOHN J. LUND, M.D., A.F.A.C.C.

INTERNAL MEDICINE - NEPHROLOGY
JOSEPH D. RUSSELL, M.D.
ROGER W. LAMANNA, M.D.

INTERNAL MEDICINE - PULMONOLOGY
LINDSEY E. de GUEHERY, M.D.

INTERNAL MEDICINE - RHEUMATOLOGY
LAWRENCE D. ISRAEL, M.D.

HEMATOLOGY - ONCOLOGY
DUDLEY B. ANDERSON, M.D., F.A.C.P.

ORTHOPEDICS
A. TYSON JENNETTE, M.D.
ROBERT A. APPERT, M.D.

OPHTHALMOLOGY
SCOTT P. BOWERS, M.D., F.A.A.O.

INDUSTRIAL MEDICINE
A. E. BURBA, M.D.

FAMILY PRACTICE
A. E. BURBA, M.D.
MICHAEL BOWEN, M.D. - STANTONSBURG
MICHAEL SUNDERMAN, M.D. - STANTONSBURG
RICHARD K. TORREY, M.D. - MIDDLESEX

FAMILY PRACTICE - AFFILIATE
J. EDWIN DREW, M.D. - MACCLESFIELD

OTOLARYNGOLOGY
BRONCHO-ESOPHAGOLOGY
SPEECH AND HEARING CLINIC
L. ASHBY ADAMS, M.D.
JOY BUNNELL, M.S.

RADIOLOGY
FRANKLIN J. YOUNGS, M.D.
D. REID TICKLE, M.D.
E. FRANK COLLINSON, M.D.
GEORGE W. EASON, M.D.

PSYCHOLOGY
GARY H. BACHARA, Ph.D.

PHYSICAL THERAPY
PAULA MICHALAK, L.P.T.

EXECUTIVE VICE-PRESIDENT
BENJAMIN BROCKWELL

CAROLINA CLINIC, INC.
1700 S. TARBORO STREET
WILSON, NORTH CAROLINA 27893
PHONE 291-1300

Cover
Letter
#1

January 24, 1986

Mr. C. McClain Haddow
Acting Dept. Administrator
Health Care Financing Administration
Room 314G Hubert Humphrey Bldg.
200 Independence Ave., SW
Washington, DC 20201

Dear Mr. Haddow:

On January 13 1986, a memo was sent from the Medicare Department of the Prudential Insurance Company of America in High Point, N. C. to all optometrists in the State of N. C., and to a few selected ophthalmologists. This memo detailed the creation of a new procedure code (W9245) with the following definition: "Postoperative cataract follow-up care by a physician other than the operating ophthalmologist (includes all services related to surgical care for 120 days from the date of surgery, and the prescription for permanent lenses and/or spectacles)." The postoperative following of cataract patients has been declared a medical act within the realm of the practice of medicine by the Medical Licensing Board of the State of North Carolina. Many physicians, upon hearing of this memo, tried to contact various and sundry representatives of the Health Care Financing Administration, Medicare, Prudential Life Insurance Company, the State Legislature, the Attorney General's Office, and the Congress of the United States. After much consultation with my ophthalmological colleagues, we have condensed a list of those persons whom we feel should have the information enclosed in this package. I have personally spoken with a few of these individuals, and they have indicated they would like as much background information and supporting documentation on this subject as is possible. I must, therefore, apologize for the extreme length of this cover letter, and the complexity of its accompanying documentation. Nevertheless, I feel that this information must be available to those of you who are in a position to make decisions which will permanently and irreversibly affect the practice of medicine and the delivery of health care in this country from this time forward. I will, therefore, attempt to give you a complete background on the subject of fee splitting, as it is viewed by the vast majority of ethical eye surgeons who constitute the N. C. Ophthalmological Society.

In September 1984, a memo was written to the members of the Carolina Clinic in Wilson, N. C. I had been a member of the Carolina Clinic one year at that time, and had become aware of a situation, whereby a Professor of Ophthalmology at a neighboring medical school was inviting optometrists in the area to undergo "training" in the postoperative care for postsurgical eye patients. This training consisted of a few hours in the office of the ophthalmologist in question, and supposedly qualified optometrists to provide postsurgical eye care for any cataract patient. The ophthalmologist also "loaned" a video tape machine and color television set to each participating optometrist with a video tape, identifying himself as the Chairman of Ophthalmology at that particular medical school. This video tape machine and television set were to be used to educate potential cataract patients as to where and from whom they could obtain the best surgical care. It was understood, that a "postoperative care fee" would be sent to any optometrist wishing to participate in this program for each patient referred in. My initial memo was quite strongly worded, and I must admit that it was written with a certain amount of anger and disgust; nevertheless, I feel that it adequately summarized the ethical concerns of most ophthalmologists in N. C.

Document #1 is a response to the memo that I had written to the members of the Carolina Clinic. A copy of this memo was inadvertently sent to the dean of medicine at the medical school where this certain surgeon held an academic appointment. It was hoped that the dean of medicine would investigate this matter and take some sort of definitive action to correct the situation. Instead, the memo was forwarded to the surgeon in question, and legal action was subsequently threatened against myself and the Carolina Clinic. The surgeon in question obviously felt that there were certain inaccuracies in this memo, and he detailed to his attorney exactly what his program consisted of. This detailed description of the surgeon's program was written by a business manager for the surgeon's practice (I wish to apologize for the notes and memos jotted in the margins of this first document. These notes were made by our clinic attorney during a meeting with the other surgeon's attorney in an attempt to avoid a lawsuit). He did concede that optometrists were allowed into the operating suite to observe surgery. He did concede that he was allowing optometrists to observe the postoperative care for patients in his clinic during an afternoon session, and that they were shown "areas, ways, and methods to make sure that the patient's eyes were in good shape considering the number of days that passed following surgery". I think is is important to note that the American Academy of Ophthalmology requires four years of medical school, a full year of internship, and between three and five years of residency and/or fellowship training at an approved hospital based school of medicine to allow its certified ophthalmologists to provide this care. It is interesting that this surgeon has created a program of education which allows nonmedical technicians (optometrists) to master these same skills in a few hours in his office. This ophthalmologist denies he is training optometrists to provide total postoperative care for any of his postsurgical eye patients. He claims that it is in direct consultation with his office; nevertheless, a postoperative care reporting form is provided to the optometrist so they can evaluate the patient, and perform this postoperative examination and simply mail the postoperative care report form back to his office. I would think that a mailed postoperative care report form, filled out by nonmedical technicians can in no way substitute for the adequate postoperative examinations which should be provided to every patient by the surgeon who performs that patient's surgery. The American Academy of Ophthalmology specifically states that this is in violation of its own code of ethics, and this certainly is not in the best interest of the patient. It is mentioned in this rebuttle memo that this practice assists those people who might be inconvenienced or in other way unable to return to the operating surgeon's clinic to be seen postoperatively. Again, the American Academy of Ophthalmology addresses this issue, and very specifically states that if postoperative care cannot be arranged with an adequately trained ophthalmologist, the surgeon is ethically bound, either to not do the surgery or refer that patient to an ophthalmologist closer to his area where such postoperative care can be provided. An interesting question might be raised as to how many optometrists were contacted by ophthalmologists engaged in this practice who did not send that particular patient in for surgical consultation. I think it is quite obvious that only those patients who are sent in by optometrists, under the arrangements listed above, will be eligible to receive a "postoperative care fee" and have the patient returned to their care. I think this squarely puts the practice detailed above in the ball park of thinly disguised fee splitting. It was mentioned in the memo that the video tape machine and color television set were not given to the participating optometrist, but were only placed on loan with them. I understand that a few ophthalmologists in North Carolina who were engaged in the distribution of television sets and video tape machines have discontinued this practice under threat of legal action by Medicare fraud investigators. Lastly, the rebuttal memo claimed to have the blessing of the Federal Government in general and the Medicare System in particular. To support this claim, the surgeon submitted document #2.

Document #2 is addressed to the Business Manager for the surgeon in question, and its origin is the Prudential Life Insurance Company in High Point, N. C., which is the administrator of the Medicare/Medicaid Program in the State of N. C. There is a Medicare heading at the top of the letter. This letter essentially says that surgical fees for cataract surgery have traditionally included components for followup services, management and/or complications. The surgeon in question is advised that providing some of the followup visits under arrangements with optometrists who bill you for these services, continues to meet the traditional definition of a global surgical fee, and the surgeon may continue to bill these surgeries in the usual manner. It also asks the surgeon in question to provide a list of providers who contracted with the surgeon for these services. Please compare this document to document #3.

Document #3 was a strongly worded Medicare bulletin sent to all ophthalmologists in the State of N. C. - again, from the Prudential Office in High Point, N. C. It says specifically, "whoever solicits or receives any remuneration, including kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing, or arranging for the furnishing of, any item or service for which payment shall be made in whole or in part, under this title, shall be guilty of a felony, and upon conviction thereof, shall not be fined more than $25,000 or imprisoned for not more that five years". It also says; "whoever offers or pays any remuneration, including any kickback, bribe or rebate, directly or indirectly, etc., etc., etc.", later in this letter is specifically mentions that optometrists, and other health care professionals are in the position to direct patients to particular suppliers or physicians pursuit to an arrangement and then receive payment from the physician for the referral, etc., etc. I find documents #2 and #3 to say exactly opposite things. Document #3 was sent to all ophthalmologists in the state, and in a nutshell, we were strongly warned not to enter into any kind of kickback or fee splitting arrangement with optometrists. Document #2 was sent in a very private manner to three ophthalmologists who were informed that their private fee splitting arrangements were o.k. with Medicare as long as they provided a list of the optometrists with whom the ophthalmologist had contracted. Prudential is a quasi governmental agency and its records are open to the Freedom of Information Act. Congress has indeed expressed an interest in finding which surgeons have established contractural arrangements with networks of optometrists to provide patients to them.

Document #4 is the postoperative care form to be filled out by the various optometrists and returned to the surgical ophthalmologist's office as detailed in the paragraphs above. Again, I wonder if any member of Congress would want to have his mother undergo a cataract extraction by a qualified ophthalmologist and then have that patient returned to an optometrist (a nonmedical technician) for postoperative care with said optometrist communicating to the surgeon by means of a one page check-off disposition sheet.

Document #5 is a copy of the 1984 current opinions of the Judicial Council of the American Medical Association regarding the fee splitting issue. The American Medical Association strongly states that: "fee splitting by one physician to another solely for the referral of the patient is fee splitting, and is improper both for the physician making the payment and the physician receiving the payment". Various ophthalmologists, engaged in the practices detailed above, feel that they are rightfully splitting the surgical fee into an operative fee and a postoperative care fee; nevertheless, I think you will find that 99% of these fee splitting arrangements are only made when optometrists send patients in to the ophthalmologists for a surgical procedure. Ophthalmologists never contact an optometrist independently who did not provide them with that particular patient and ask them to participate in the care of that postsurgical patient. Hence, this is obviously very thinly disguised fee splitting.

Document #6 is a complete copy of the code of ethics of the American Academy of Ophthalmology. The various issues raised above are contained in the Academy's code of ethics. Most successful ophthalmic surgeons are members of the American Academy of Ophthalmology as it is the certifying body for their specialty boards; nevertheless, any ophthalmologist who engages in the above practices is squarely in violation of his own academy's code of ethics.

Document #7 is a symposium on ethics in ophthalmology conducted by members of the Ethics Committee of the American Academy Ophthalmology. These serve to expand and further illuminate the various ethical rules which are adopted by the Academy. You may find rule 7 regarding delegation of services and rule 8 regarding postoperative care to be most applicable in this situation. I believe the rules are totally self explanatory and clear on this issue.

Documents 8, 9 and 10 are advisory opinions on the Code of Ethics of the American Academy of Ophthalmology. These advisory opinions are extended interpretations of the various rules in the Academy's Code of Ethics. I have provided extended advisory opinions on rules 8 and 9 as listed above. Document 10 deals specifically with the issue of splitting a surgical fee with an optometrist who provides post surgical care. The Academy states unequivocally that "simply agreeing to this arrangement would clearly and unquestionably violate the code of ethics". Advisory opinion 10 clearly points out that even payments from ophthalmologists to optometrists for referrals where the optometrist does perform some services may raise serious problems. Such payments may lead to unnecessary referrals, unnecessary cost, and referral to ophthalmologists who may not be qualified to handle particular patients' problems. Also, automatic re-referrals to optometrists would be objectionable for the same reason and may not be in the best interest of patients. Such payments in exchange for referrals are unethical; indeed, they are illegal under most state laws. The Federal Law bars payments of this kind in most circumstances where Medicare or Medicaid funds are involved. Advisory opinion 10 also quite clearly states that, "it is the operating surgeon's obligation to examine the patient postoperatively and insure that his medical condition is progressing as well as possible." This obligation does not end the morning after surgery. A standing arrangement for postoperative care for all patients clearly violates the Code of Ethics of the American Academy of Ophthalmology. Lastly, advisory opinion 10 states that "except in exceptional circumstances, ophthalmologists should not pay optometrist for a refraction."

The Medical Licensing Board of the State of N. C. has received complaints about ophthalmologists engaged in this type of fee splitting arrangement over the past year and a half. It is the feeling of the Medical Licensing Board that the postoperative care and following of cataract patients is totally within the realm of the practice of medicine, and as such, is appropriately regulated by the Board of Medical Examiners. A memo to this effect was sent by the Board of Medical Examiners in November 1985 to every licensed ophthalmologist in the state. I have enclosed a copy of this directive for your records (document #11). It should be noted that Medical Licensing Board was created by a very broad empowering act of the State Legislature, which gave the Medical Licensing Board the sole authority in the State of North Carolina to define the parameters and boundaries of the practice of medicine and to regulate such practice within this state. The opinion and decisions of the Medical Licensing Board therefore carry the force of Law.

Tradiitionally, a surgeon's duty to a pateint has not ended when the patient is wheeled out of the operating theater. Indeed, many surgical specialists will tell you that the careful preoperative and postoperative management of a surgical patient is much more critical to the final outcome than the procedure itself. A surgeon's duty to his patient includes a careful history and meticulous examination, Interpretation of various diagnostic and laboratory tests, careful judgement as to which procedure, if any, is in the patient's best interest, the performing of the procedure itself, the careful postoperative following of that patient, and appropriate therapeutic modifications in the postoperative management to insure that the patient recovers completely. I am sure it is no surprise to the decision makers in HCFA and Medicare that many patients experience problems hours, days, weeks, and months after their procedure. Consigning these patients to non medical technicians (optometrists) who have no basic science training in pharmacology, physiology, microbiology, anatomy, infectious disease, or biochemistry nor hospital based or clinical training in internal medicine, surgery or the pre and postsurgical management of ophthalmic patients is tantamount to patient abandoment. It should be noted by HCFA and Medicare, that the majority of states still do not allow optometrists to use diagnostic drugs. Only four states in the union allow optometrists to use therapeutic drugs. Specifically in North Carolina, the 1976 Therapeutic Drug Bill was designed to allow optometrists to diagnose and treat certain basic eye conditions because it was felt that at that time, there was a large segment of the rural population which was physically remote and had no access to qualified ophthalmic care. The law in no way, shape or form intended for optometrists to examine for surgery, make surgical recommendations, prepare patients for surgery, do surgery or participate in the postoperative management of patients. The professional aspirations of optometrists are light years beyond their qualifications or the spirit and intent of the Therapeutic Drug Act of 1976. The Medical Licensing Board of North Carolina has specifically examined this issue and their decision culminated in the memo sent to all ophthalmologists in November 1985 (document #11).

Therefore, it was to the great surprise of the entire ophthalmic community of North Carolina when Prudential Life Insurance Company issued a Medicare bulletin dated January 13, 1986. This Medicare notice detailed the creation of procedure code W9245: "postoperative cataract followup care by physician other than the operating opthalmologist (includes all services related to surgical care for 120 days from the day of surgery and the prescription for permanent lenses or spectacles). The ophthalmic community, and indeed, the entire medical profession in the State of North Carolina is shocked that the Federal Government through its Medicare regulators would attempt to supercede the duly constituted and licensed authority of the Medical Licensing Board of North Carolina, which has already examined and ruled on this issue. Indeed, when you compared document #12 with the preceding Medicare bulletins we again see striking contradictions. First, all ophthalmologists in the State of North Carolina are warned to avoid any kickback or fee splitting schemes. Next, three ophthalmic practices in the State of North Carolina are given private assurances that their fee splitting arrangements are o.k. with Medicare, as long as Medicare has a list of the optometrists with whom they have contracted (because Prudential is administering Medicare and Medicaid in this state, its records are open to the public under the Freedom of Information Act). Next, the Medical Licensing Board examines the whole issue, and clearly decides that the postoperative care and following of cataract patients is indeed a medical act, and it is only to be provided by physicians. Next, Medicare and HCFA quietly send out notices to the ophathalmologists involved in the original fee splitting schemes that they should probably withdraw their television sets and video tape machines (this might be construed as a gift!), and they should discontinue the policy of splitting off a portion of the surgical fee and mailing it back to the referring optometrist for each patient referred in (this might indeed look like fee splitting!). Now Medicare takes the astounding position that fee splitting is wrong, but institutionalized fee splitting (whereby Medicare will split the fee for the operating surgeon and pay the postage back to the referring optometrist) is perfectly acceptable in the eyes of the government. This new Medicare Code essentially states that the Federal Government recognizes optometrists as legitimate providers of postoperative care, despite the fact that the North Carolina Board of Medical Examiners has specifically ruled that this is within the realm of the practice of medicine and must be provided by an M. D. The real crux of the matter is, that the Federal Government now seems to feel bold enough to intervene in the various states and redelineate the boundaries and limitations of the various professions. I was under the impression that the North Carolina Board of Medical Examiners was constituted and licensed to perform that function. Apparently, Medicare now feels that it has taken over that function from the Medical Licensing Board.

I have also enclosed a resolution by the North Carolina State Ophthalmological Society, which formally adopted the American Academy's Code of Ethics as the statewide standard of ethical behavior (document #13). It also adopts the Academy's enforcement provision (including recourse for those accused of ethical violations), such that the state society can remove those members found guilty of unethical professional conduct.

The optometrists of the State of North Carolina have already seized upon this latest Prudential Memo as proof positive that the Federal Government intends to redelineate the practice of optometry versus opthalmology in favor of optometry. They feel that they have won through administrative rule what they have failed to obtain through appropriate education and training, legislative mandate, or judicial order. Indeed, some optometrists are already making noises that, because they are now recognized by the Federal Government as legitimate providers of postsurgical care from the first postoperative day on, they now have the Federal Government's blessing to demand hospital privileges to occasionally provide such care.

Adverse reactions commonly occur in the elderly postoperative cataracts patient, and optometrists are simply not equipped to deal with these contingencies. How many optometrists have complete resuscitation equipment available in their offices (almost all ophthalmologists do have a crash cart in their office). Patients are often in need of intravenous medications to control postoperative pressure rises with intractable nausea and vomiting. If an optometrist cannot get an elderly patient to keep down a dose of Diamox or oral glycerin, is he then going to start an I. V. in the office and administer systemic Mannitol? This is totally beyond the scope and training of most optometrists, but is often a common necessity in the elderly postoperative eye patients. Many optometrists say that they would simply return the patient to the care of the ophthalmologist under such circumstances, and in many instances, these optometrists are referring patients several hours drive away because that is the only place they can participate in these postoperative care fee schemes. Many of these patients will not tolerate a long car drive and many patients would suffer care was delayed several hours. I think it is quite obvious that arguments in favor of these schemes touting the increased convenience to the patient are largely exaggerated, and in many instances, can actually be dangerous to the patient. It should be also be noted that ninety plus percent of all persons in North Carolina within 15-20 minutes driving time of a Board Certified Ophthalmologist. Therefore, these arrangements are obviously more for the convenience of the operating surgeon and his referring optometrist than they are for the patient. Postoperative care of cataract patients often involves the need for laser surgery, suture removal or adjustment, and paracentesis. These are surgical procedures which are often needed in the immediate postoperative period on an emergency basis. Again, optometrists are totally unqualified to perform these services (nor are they licensed to do so in any State of the Union), but their interpretation of the Medicare Law would lend credence to their argument that they are now recognized as providers of this care as well.

Many of the optometrists involved in these fee splitting schemes are referring in patients who are not in need of the surgical care they are receiving. I am sure HCFA and Medicare have many, many documented instances of unnecessary surgeries. I don't know whether your figures have borne this out yet, but most of this unnecessary surgery is performed at these large "cataract mills" who use a fee splitting arrangement to contract with large networks of optometrists. I am enclosing a small sample of documentation that I have been able to obtain through my own practice, whereby a certain patient was misinformed as to the level of her visual function and disability, and was told that she was in need of surgery to "preserve her vision". I believe the accompanying narrative (document 14-A) is self explanatory. The business card mentioned in memo 14-A has been xeroxed and reproduced in document 14-B. I have also enclosed the narrative summary by another physician in my hometown who has well documented the case of an 84 year old lady who was told by another optometrist who participates in these same fee splitting schemes that she was in need of "immediate surgery to preserve her vision", and that she was strongly encouraged to go to one of these large cataract practices for this care. This patient sought second opinion with another ophthalmologist who was kind enough to detail his examination in a narrative summary. Obviously, cataract surgery would not have benefitted this lady, and she was being scheduled for an obviously unnecessary procedure. The story of this same lady as documented by her personal family physician is also enclosed (documents 15-A and 15-B). The handwritten instructions by the optometrist instructing her to report to his office in the next few days for this "immediate surgery to preserve your vision" is submitted as well (document 15-C). I am sure HFCA has many, many similar such documented episodes of unnecessary surgery as does Congressman Claude Pepper's Subcommittee on Health and Aging. I am also enclosing a notice by the John Kenyon Eye Center in Jeffersonville, Indiana. This notice went out to a large number of optometrists, and informed them that the ophthalmologists involved in this certain eye center were no longer going to provide prescriptions or glasses or contact lenses on any new patients. All new and followup patients will be referred to an optometrist in that area for refraction and care as needed prior to and following their eye surgery. In other words, these surgeons are refusing to provide postoperative refraction to their patients even when asked to do so by the patient. This is incomprehensible. It naturally appeals to optometrists who provide large numbers of patients to these "surgery only" eye centers, but it represents a refusal by operating surgeons to provide a traditional and necessary service to the visual recovery of their postsurgical eye patients.

Lastly, I wish to point out that ophthalmology is not the only branch of medicine faced with potential widespread abuse in fee splitting networks. Chiropractors could very well receive "postoperative care fees" for any disc patient referred in to an neurosurgeon. Podiatrists could provide "total postoperative care" for hip and knee replacement patients. A dentist could provide large numbers of patients with a variety of oral pathology to either oral surgeons or ENT surgeons in exchange for a portion of the global surgical fee. Family practitioners could conceivably direct their patients to only those surgeons which would allow them to assume the postoperative care for a "reasonable" portion of the surgical fee. This could be a real nightmare for medicine as we know it. I would hope that officials at HCFA and Medicare will take this information into careful consideration and re-evaluate the recent memos sent out by Prudential of High Point, N. C. As I understand it; N. C. State Medical Society, State Ophthalmological Society and the Medical Licensing Board are considering various legal options to try and resolve this issue as soon as possible. It is my hope in providing you with this information that this issue could be examined carefully and thoughtfully, and a reasonable course of action could be taken to avoid legal recourses. In talking to Mr. Al Walsh of Prudential Life Insurance (who claimed to be the author of this memo), I discovered that he was directed to write this letter by someone in the Regional Office. I called Mr. Haddow's office and talked to his assistant, J. O'Brian, and he was totally unaware of any such decision by HCFA. Perhaps this decision has been made without full consultation of the policy makers at the head of HCFA. It is my hope it can be reversed before too much damage is done.

I hope this information is helpful to you. Please do not hesitate to contact me at the above listed address or telephone number if I can provide any further information which you might find helpful.

Sincerely yours,

Scott P. Bowers, M.D.

SPB/btb

Enclosures

COVER
Letter
#2

April 8, 1986

Ken Nelson, M.D.
Office of Inspector General
Dept. of Health and Human Services
Room 5246 North Bldg.
330 Independence Ave. SW
Washington, DC 20201

Dear Dr. Nelson:

Please find enclosed a long cover letter and extensive list of supporting materials documenting the genesis of various fee-splitting schemes between optometrists and ophthalmologists in the State of North Carolina. This subject has been hotly debated in North Carolina for over a year and half. In order for you to completely understand the origin and importance of the accompanying documentation, I have composed a long cover letter which was sent out several months ago to the following persons: The entire N.C. Congessional Delegation, our two U.S. Senators, several prominent members of the N.C. Legislature, the Attorney General of N.C., The Bureau of Eligibility, Reimbursement and Coverage, The Medicare Regional Office in Atlanta, the Medicare Office in High Point, N.C., Congressman Claude Pepper's Subcommittee on Aging and Health, Dr. Otis Bowen at Health and Human Services, and the Medical Licensing Board of the State of N.C. If you will read through the initial cover letter and peruse the accompanying documentation (documents 1-16), you will pretty well understand the structure and framework of the fee-splitting schemes which presently exist in the State of N.C., and how they have been justified (rightly or wrongly) by those persons involved in them as having the blessing of the Health Care Financing Administration. You will also find the objections of Organized Medicine, Organized Ophthalmology, State Medical Licensing Board, and the Attorney General of the State of N.C. Specifically, the Board of Medical Examiners of the State of N.C. and the Attorney General object to these arrangements because they violate the prerogative of the State of North Carolina to define and regulate the practice of medicine in this state.

Organized Medicine and Organized Ophthalmology object to these arrangements because they clearly violate the ethical cannons of the State and National Ophthalmological and Medical Societies.

Document 17 is a reply to this original letter and supporting materials from Dr. Al Walsh who runs the Medicare Division for the Prudential Life Insurance Company in High Point, N.C. I have discussed the situation, both in letter and on the telephone with Mr. Walsh; and he has made it quite clear that he feels free to interpret the State Laws of N.C. as he sees fit. He has refused to recognize the duly constituted authority of the Medical Licensing Board in N.C. (which is charged with defining and regulating the practice of medicine in the state), and has indicated that he will continue to provide federal monies to optometrists under the new procedure code which reimburses optometrists for the immediate postsurgical management of cataract patients. Common sense and logic would allow any reasonable person to see that these "postoperative care fees" are thinly disguised kickbacks - now institutionalized as government sponsored fee-splitting through the Medicare Program. We have documentation that large numbers of patients are being sold to unscrupulous ophthalmologists by large networks of optometrists who refer these patients in for surgery (whether they really need it or not) and are then in a position to receive a large "postoperative care fee" from Medicare. The "postoperative care fees" initially were being paid in cash directly to the optometrists by the referring physician. Complaints were filed at that time to various members of Congress and to the State Medical Licensing Board here in N.C. Mr. Peter Reinecke, chief investigator for Congressman Pepper's Committee on Aging, assured me that he would forward these complaints to the proper officials in HCFA and the Inspector General's Office, and that some action would be taken. Medicare Bulletin #84-4 was issued from the Prudential Life Insurance Office in High Point, N.C. in December 1984 after these initial complaints were filed, and all physicians in the state were warned through this bulletin not to enter into any kind of kickback or rebate arrangement. The most important sentence in this Medicare Bulletin (document #3) is on the second page: "The opportunity to generate a fee is itself a form of remuneration. The offer or receipt of such fee opportunities is illegal if intended to induce a patient referral". Mr. Walsh's reply (document #17) claims to have the blessing of the Inspector General's Office in implementing these new arrangements, and that "no impropriety existed as long as a professional service was being rendered". Medicare Bulletin 84-4 (document #3) says exactly the opposite. There is a serious conflict here which must be resolved one way or the other.

Mr. Walsh's reply also eludes to the issue of offering video tape machines and television sets and states that "through subsequent discussion with Health Care Financing Administration, the offering of VCR's, etc., was discouraged, and as far as we know, was discontinued". I find it shocking that the good faith reporting of fraud and abuse violations were not aggressively investigated and prosecuted, but that these persons were "discouraged" from continuing these fraud and abuse violations. In the State of N.C., it costs an average of fifteen dollars a day to rent a video tape machine and eight dollars a day to rent a color television set. Many optometrists had these video tape machines and color television sets in their office for months or years at a time. I think a case can be made that a substantial gift was indeed given to many optometrists in exchange for the referral of large numbers of cataract patients. The fact that HCFA has documentation that these abuses did indeed occur and has not investigated or prosecuted them is deeply disturbing. Although many of the ophthalmologists originally involved in these television and video recorder "loans" have subsequently asked the optometrists to return the equipment, it does not change the fact that huge numbers of patients were generated through these illegal schemes; and that in many cases, these large "stables" of referring optometrists exist intact up until the present time.

Document 18A is a formal response from the Attorney General of N. C. concerning the legal authority of the Medical Licensing Board. This letter is self explanatory, and shows the support of the Attorney General for the Medical Licensing Board in this matter. Document 18B is a second letter, addressed to a colleague of mine, which cites specific state law empowering the Board of Medical Examiners to seek an injunction against the new Medicare Codes or to revoke the Medical License of any physician in this state who engages in prohibited conduct, including ethics violations. It would be most unfortunate for Medicare if physicians who claim the blessing of the Federal Government to split fees with optometrists lost their license for ethics violations in this state. I think this would be extremely embarrassing for the Federal Government in general, and Medicare in particular.

Document 19 is a reply to Mr. Walsh from myself detailing the objections of Organized Ophthalmology and Organized Medicine to these new procedure codes. In this letter I also eluded to the fact that special treatment seems to have been afforded a few large ophthalmology practices in this state involved in fee-splitting schemes. Many ophthalmologists in this state feel that a case can be made for preferential treatment by government officials toward a few large (and admittedly very profitable) private ophthalmic practices.

Document 20 is a response from Robert Striemer at the Bureau of Eligibility, Reimbursement and Coverage. As you can see from Mr. Striemer's letter, he takes the position that "although the N. C. Board of Medical Examiners objects to optometrists providing postoperative care for cataract patients, is apparently not in violation of State Law". I can't get anyone in HCFA to understand that the N. C. Board of Medical Examiners is the law as far as the definition and regulation of the practice of medicine in this state. In addition, both Mr. Striemer and Mr. Walsh claim to have the blessing of the Inspector General's Office in these thinly disguised fee splitting schemes. I wonder how fully informed the Inspector General's Office has been kept by HCFA in regards to this matter.

I hope all this information is helpful to you. Please do not hesitate to call my office at the above listed address or number if I can provide any information to you about this very unfortunate state of affairs.

Most sincerely,

Scott P. Bowers, M. D.

SPB/btb

Enclosure

---

promotional

system works

come

If postop forms

forms come back

normal findings

September 27, 1984

Dear

The following is the list of inaccuracies that were contained in the memo written by to his fellow colleagues at the . It is also obvious that some of these memos got into the hands of other people beyond the itself.

Inaccuracy #1 - "Optometrists in this area are being invited to assist this ophthalmologist in surgery..." This is not true. The visiting optometrist is allowed to view surgery as part of a continuing education program approved by the Board of Examiners of the North Carolina Optometric Society. This is for observation only.

not hired to examine our pt

Inaccuracy #2 - "...and then to spend the day in the office examining postoperative patients." This is also inaccurate. They are observing the postoperative care for patients in our clinic and are then shown areas, ways, and methods that we make sure that the patient's eyes are in good shape considering the number of days that have passed following surgery.

we are seeing pt day after surgery & complete care

Inaccuracy #3 - "This training then enables the optometrist to provide total postoperative care for any postsurgical eye patients;..." This is also inaccurate. There is no way that the total postoperative care will be provided by the optometrist. It is in direct consultation with us and assists those people who might be inconvenienced or in any other way unable to return to our clinic

everyone that cares for pt must

Louisburg
Pinehurst } Satellite clinic

If severe inflammation who to call

showed list

postop pt

technically correct
100% true

An office production:
audio-visual at Ec
by professional - not
show my face

to be seen postoperatively and then for us to follow up with communications with that optometrist who is seeing the patient on our behalf. , who participates in postop care

+ [illegible] thru [illegible] state [illegible] [illegible]

Inaccuracy #4 - "..., it is understood that a postoperative care fee will be sent to the optometrist when any cataract patient is referred to the .." This is a horrendous distortion. A postoperative care fee is not going to be provided to any optometrist for a cataract patient referred. It is for professional services rendered on those patients ~~they are~~ seeing postoperatively in consultation with us.

illegal to accept fee for postop care without referral

Medicare approved method for reimbursement

Inaccurracy #5 - "The fee mentioned is $150." The accurate statement is that we have been in collaboration and consultation with Prudential Medicare in who went through the Health Care Financing Administration to see to it that we could reimburse optometrists who were seeing the patients postoperatively in coordination with our efforts ~~from here~~.

$105 approved by Medicare

Regulations available

explained

one tape only

not showing his expertise

Inaccuracy #6 - "This ophthalmologist is also giving a free Sony Betamax and RCA XL-100 color television set to each participating optometrist and, of course, three tapes showing his wonderful expertise in the operating room are provided..." The inaccuracy there is that we are not giving anything to anyone. We are placing on loan with the optometrist, whether they are participating in our program or not, an educational tape which in no way suggests to that patient in any way, shape, or form that they should have their surgery by or be referred to the

patient information tape + we provide the audio-visual on loan to optometrist to be specifically told no way guarantee

referring to us is not a precondition for receiving Education + Equip. + Documents + [illegible] claims - any defects will be responsibility of [illegible] per Educ

Inaccuracy #7 - "The Betamax and the color TV set are, of course, free for the optometrist to keep permanently." This is an inaccurate statement because we have put it on loan with them. They do not accept any responsibility for the set and we are free to pick that set up at any time.

Inaccuracy #8 - "This blatant attempt by the chairman of a department at a major medical school to set up a thinnly disguised fee splitting arrangement with

[redacted]

No reimbursement until forms [illegible] [illegible] to [illegible] [illegible] [illegible]

library of tapes. ie glaucoma

~~HCF~~ Health Care Financing
Private medicare office
approve it

a large group of primary eye care providers in this state is not only unethical, it is probably illegal." The fact of the matter is that this is a result of a carefully documented program which has been set up in coordination with the Medicare system in North Carolina to allow us to reimburse optometrists for services provided and rendered in the postoperative care phase. The inaccuracy is that it is not unethical. The United States of America endorses the idea. It is absolutely legal in that the Medicare system in coordiation with the Health Care Financing Agency approves of exactly what it is that we are doing.

Inaccuracy 9 - "Nonmedical personnel are being actively trained to deliver postsurgical medical services on the campus of the
by one of their active department heads..." This is a flagrant statement. They are not being trained at the . Dr.
didn't even realize or recognize that the
: is a private institution, and our work here is done as any other practice would be carried out. I would hasten to add, however, that we are also assisting residents and bringing them over here to discuss courses and training in ophthalmology, but what is done here in relation to the overall patient is the work of the

to train
at medical
Medical School
not continuing

Inaccuracy #10 - This blatant attempt by a buccaneer surgeon to set up a fee splitting network with inadequately trained eye care providers who will be in fact managing immediate postop surgical patients through their most vulnerable postoperative period is tantamount to patient abandonment." Again, this is a flagrant misrepresentation of the facts. The is following these patients closely in coordination and conjunction with the optometrists in the local area where the person was returned following surgery. It is important to know that there are many people who are receiving postoperative care who cannot return to a clinic from a long way away, and this is a way to make sure that that patient's eye is quiet and recooperating properly.

[illegible] out
A reminder
encourage
that no [illegible] would
opted [illegible]
see what they
see — them
screening &
and. Have to
have come here
before they can
see pt 50 mi
17 within
of equally
[illegible]
postop
care

1/2 ophthal
[illegible]

[illegible]
& spend
day

we are finding it difficult to keep our heads about such a flagrant misrepresentation of the truth, and we look forward to your continuing steady counsel in this matter. We appreciate all of the help that you have been to us in the past, and we look forward to your quick response with this as to how we might proceed to establish what the truth is and to make this gentleman realize the errors that he has made so that he might be able to set the record straight. Thanks again.

Sincerely,

Clinic Administrator

Medicare

The Prudential
Insurance Company
of America

Box 2126
High Point, N. C. 27261
Telephone: (919) 889-8175

Prudential

72

September 20, 1984

Dear

Dee Bryson, HCFA On-Site Representative, contacted the Regional Office about your proposal for providing post-operative cataract services (routine follow-up visits). The surgical fees for cataract surgeries have traditionally included components for follow-up services, management and/or complications. The Regional Office advised that providing some of the follow-up visits under arrangement with optometrists who bill you for these services continues to meet the traditional definition of a global surgical fee. You may continue to bill these surgeries in the usual manner.

Medicare would not be liable for claims from the optometrists, etc. Any claims so identified would be denied as duplicate services. In order for us to monitor potential duplicate payments, please provide us a list of the providers you contract for these services.

Enjoyed working with you, advise if I can be of further assistance.

Sincerely,

Virgil Tuttle

Virgil Tuttle, Associate Manager
Medicare Claims Division

caa/MCD

cc: Dee Bryson, RHIR

Dr. Clark,
I am sending this to you at Dr. Riddick's request.
R. Marchant, [illegible]

Prudential

#6

MEDICARE BULLETIN

3

N.C. 84-4
December, 1984

KICKBACKS, REBATES - It has come to our attention that some Durable Medical Equipment (DME) Suppliers may be offering rebates, kickbacks, and/or other inducements to respiratory therapists or other allied health personnel to refer patients needing home oxygen, equipment and supplies. Instances of similar arrangements between optometrists and ophthalmologists have been reported, wherein the optometrist refers the patient for a flat fee or the opportunity to provide post-operative follow-up care, which may result in increased cost to the Medicare Program. Depending on the nature of the offer and the nature of the encouragement, these or similar arrangements may be in violation of a criminal statute, Section 1877(b) of the Social Security Act, that provides as follows:

1877(b)(1) Whoever solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind --

(A) in return for referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service for which payment may be made in whole or in part under this title, or

(B) in return for purchasing, leasing, or ordering any goods, facility, service, or items for which payment may be made in whole or in part under this title,

shall be guilty of a felony, and, upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --

(A) to refer an individual to a person for the furnishing, or arranging for the furnishing, of any item or service for which payment may be made in whole or in part under this title, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering, any good, facility, service, or item of which payment may be made in whole or in part under this title,

shall be guilty of a felony, and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to --

(A) a discount or other reduction in price obtained by a provider of services or other entity under this title if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under this title; and

(B) any amount paid by an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.

CFA has learned that, in some instances, therapists, optometrists, or other ealth professionals in position to direct patients to particular suppliers or hysicians, will refer a patient and pursuant to an arrangement, then receive ayments from the physician for the referral, or from the DME supplier for etting up the necessary equipment, instructing the patient in the use of the quipment, or performing monthly maintenance on the equipment. The statute, owever, proscribes payment or receipt of any remuneration that is intended to nduce a referral. The opportunity to generate a fee is itself a form of emuneration. The offer or receipt of such fee opportunities is illegal if ntended to induce a patient referral. Thus, a provider who induces patient eferrals by offering fee-generating opportunities is offering illegal emuneration, even if the amount involved is no more than his or her usual . Such arrangements are considered a violation of the criminal statute nd will be investigated accordingly.

pecific instances of this type of activity should be reported to our office, r the regional office of the Office of Health Financing Integrity, Office f the Inspector General (OIG) of the Department of Health and Human Services or investigation. The phone number of the special agent in charge of nvestigations in the OIG's Atlanta Regional Office is (404) 242-5020. The IG also maintains a national toll-free hotline, (1-800-368-5779) that can be sed to report program abuse. You may also contact our Program Integrity nit at (919) 884-3550, 3551, or 3495. Requests for confidentiality will be espected.

HYSICIAN SERVICES BY NON-PHYSICIANS: Hospital or office visits, physical xams, prescribing of medication, and assisting at surgery are considered physician" services, and are not reimbursable by Medicare when rendered by PA, FNP, non-physician surgical assistant, etc. (Certain CRNA services are xempt. See Bulletin 83-4, 10/83.)

nly those non-physician services "incident to" a physician's personal care re eligible when performed as an adjunct to that care. Clinical laboratory, KG's, x-rays, injections, etc., are examples of eligible services performed y a physician's employee. Physician services are not covered unless ersonally rendered by the doctor, and billing of non-covered services of 's, FNP's, etc., as though they were rendered by the physician may constie intentional misrepresentation of material facts, punishable under PL 2-603 (42 USC 1395) by a fine of not more than $10,000 or not more than ne year in prison, or both, on each count. Each claim so submitted would

POST-OP REPORT FORM

DOCTOR: ____________________ PHONE: ____________

PATIENT'S NAME: ____________________ DATE OF BIRTH: ____________ SEX: ______

FOLLOW-UP REPORT

Time Since Operation: Week(s) ____ Month(s) ____ DATE: ____________

Complaint: ________________________________

RIGHT EYE/LEFT EYE (circle) PAm ________ date ________

V/A: without 20/______ FC HM LP NLP

V/A: with ______ sphere ______ cylinder ______ axis 20/______ FC HM LP NLP

IOP: __________ mm. Hg.

EXAMINATION OF TREATED EYE ONLY

CLARITY OF OPTICAL MEDIA:

Clear ______ Slightly Hazy ______ Moderately Hazy ______ No Red Reflex ______

	None	Mild	Med. to Severe
CORNEAL STATUS:			
Striae	____	____	____
Staining	____	____	____
ANTERIOR CHAMBER:			
Flare	____	____	____
Cells	____	____	____
Corneal Precipitates	____	____	____
IOL Precipitates	____	____	____
Cells/Flare Present After 6 Weeks	____	____	____
PUPIL STATUS:			
Displacement	____	____	____
Disfigurement	____	____	____
IOL STATUS:			
Pigment Dusting	____	____	____
Decentered	____	____	____
POSTERIOR CAPSULE STATUS:			
Capsular Haze With Decreased VA	____	____	____

ANTERIOR CHAMBER DEPTH:

Normal ______ Shallow ______

Consultation with ____________________ and

recommendations: ____________________

Disposition: ____________________

Return: ____________________

Signed Date

If any severe pain and/or rapid decrease in vision develops, an immediate consultation is in order.

North Carolina Medical Society
222 N. PERSON STREET • P.O. BOX 27167 • RALEIGH, NORTH CAROLINA 27611 • 833-3836

C. WILLARD CAMALIER, III
Executive Assistant
Health Planning

5

October 19, 1984

Scott Bowers, M.D.
Carolina Clinic, Inc.
Wilson, N.C. 27893

Dear Dr. Bowers:

Pursuant to your request I am enclosing a copy of the "1984 Current Opinions of the Judicial Council of the American Medical Association" regarding the fee-splitting issue. I was unable to locate an AMA opinion on the issue of patient abandonment.

I hope this information satisfies your request and if we can be of any further assistance, please let us know.

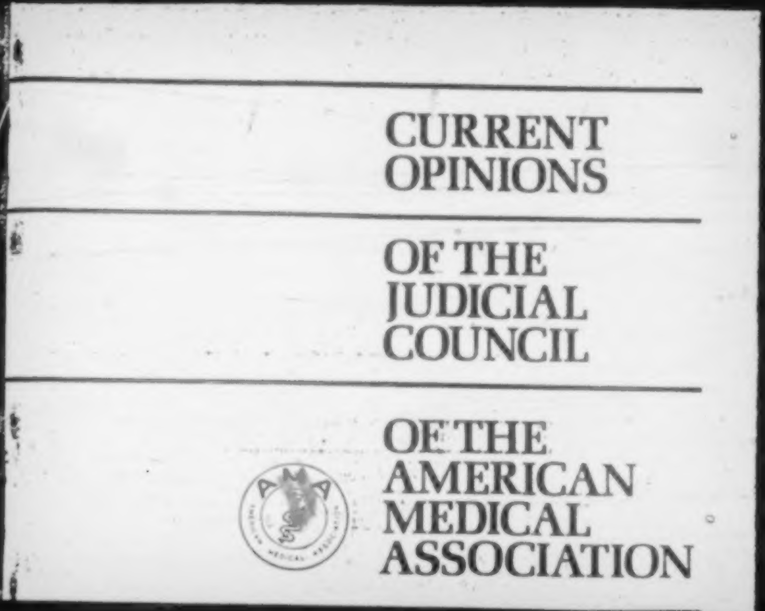
Sincerely,

C. Willard Camalier
C. Willard Camalier, III
Executive Assistant
Health Planning

CWC/smk

Enclosure

cc:



CURRENT
OPINIONS

OF THE
JUDICIAL
COUNCIL

OF THE
AMERICAN
MEDICAL
ASSOCIATION

1984

(d) the quality of performance;
(e) the nature and length of the professional relationship with the patient; and
(f) the experience, reputation and ability of the physician in performing the kind of services involved. (II)

6.02 **FEES: GROUP PRACTICE.** The division of income among members of a group, practicing jointly or in a partnership, may be determined by the members of the group and may be based on the value of the professional medical services performed by the member and his other services and contributions to the group. (II)

6.03 **FEE SPLITTING.** Payment by one physician to another solely for the referral of a patient is fee splitting and is improper both for the physician making the payment and the physician receiving the payment.

A physician may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source for the purchase of drugs, glasses or appliances.

In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the physician on matters of referral. All referrals and prescriptions must be based on the skill and quality of the physician to whom the patient has been referred or the quality and efficacy of the drug or product prescribed. (II)

6.04 **FEE SPLITTING: CLINIC OR LABORATORY REFERRALS.** Clinics or laboratories that compensate physicians based solely on the amount of work referred by the physician to the clinic or laboratory are engaged in fee splitting which is unethical. (II)

6.05 **FEE SPLITTING: DRUG PRESCRIPTION REBATES.** A physician may not accept any kind of payment or compensation from a drug company for prescribing its products. The physician should keep the following considerations in mind:
(1) A physician should only prescribe a drug based on his reasonable expectations of the effectiveness of the drug for the particular patient.
(2) The quantity of the drug prescribed should be no greater than that which is reasonably required for the patient's condition. (II)

CODE OF ETHICS
OF THE
AMERICAN ACADEMY OF OPHTHALMOLOGY

Effective
January 1, 1984

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PREAMBLE

The Code of Ethics of the American Academy of Ophthalmology applies by its terms solely to the Academy and to its Fellows and Members in their capacities as Fellows and Members of the Academy, and not in any other capacities, and is enforceable solely by the Academy. The Academy does not suggest or imply that any other medical society, organization, or association should adopt, implement, or enforce codes or standards of ethics which are the same as or similar in any respect to the Academy's Code of Ethics.

A. PRINCIPLES OF ETHICS

> The Principles of Ethics form the first part of this Code of Ethics. They are aspirational and inspirational model standards of exemplary professional conduct for all Fellows or Members of the Academy in any class of membership. They serve as goals for which Academy Fellows and Members should constantly strive. The Principles of Ethics are not enforceable.

1. **Ethics in Ophthalmology.** Ethics are moral values. An issue of ethics in ophthalmology is resolved by the determination that the best interest of the patient is served.

2. **Providing Ophthalmological Services.** Ophthalmological services must be provided with compassion, respect for human dignity, honesty and integrity.

3. **Competence of the Ophthalmologist.** An ophthalmologist must maintain competence by continued study. That competence must be supplemented with the talents of other professionals and with consultation when indicated.

4. **Communication with the Patient.** Open communication with the patient is essential. Patient confidences must be safeguarded within the constraints of the law.

5. **Fees for Ophthalmological Services.** Fees for ophthalmological services must not exploit patients or others who pay for the services.

6. **Identification of the Deficient Ophthalmologist.** Those ophthalmologists who are deficient in character, or who engage in fraud or deception, should be identified to appropriate authorities.

7. **Ethical Rules.** It is the duty of an ophthalmologist to place the patient's welfare and rights above all other considerations. To this end one must subscribe to ethical rules which are for the benefit of the patient.

B. RULES OF ETHICS

> The Rules of Ethics form the second part of this Code of Ethics. They are mandatory and directive specific standards of minimally-acceptable professional conduct for all Fellows or Members of the Academy in any class of membership. The Rules of Ethics are enforceable for all Academy Fellows and Members.

1. **Competence.** An ophthalmologist is a physician who is educated and trained to provide medical and surgical care of the eyes and related structures. An ophthalmologist should perform only those procedures in which the ophthalmologist is competent by virtue of specific training or experience or is assisted by one who is. An ophthalmologist must not misrepresent credentials, training, experience, ability or results.

2. **Informed Consent.** The performance of medical or surgical procedures shall be preceded by appropriate informed consent.

3. **Clinical Experiments and Investigative Procedures.** Use of clinical experiments or investigative procedures shall be approved by adequate review mechanisms. Clinical experiments and investigative procedures are those conducted to develop adequate information on which to base prognostic or therapeutic decisions or to determine etiology or pathogenisis, in circumstances in which insufficient information exists. Appropriate informed consent for these procedures must recognize their special nature and ramifications.

4. **Other Opinions.** Additional opinion(s) shall be obtained if requested by the patient. Consultation(s) shall be obtained if required by the condition.

5. **The Impaired Ophthalmologist.** A physically, mentally or emotionally impaired ophthalmologist should withdraw from those aspects of practice affected by the impairment. If the ophthalmologist does not withdraw, it is the duty of other ophthalmologists who know of the impairment to take action to assure withdrawal of the impaired ophthalmologist.

6. **Preoperative Assessment.** Surgery shall be recommended only after a careful consideration of the patient's physical, social, emotional and occupational needs. The preoperative work-up must document the indications for surgery. Performance of unnecessary surgery is an extremely serious ethical violation.

7. **Delegation of Services.** Delegation is the use of auxiliary health care personnel to provide eye care services for which the ophthalmologist is responsible. An ophthalmologist must not delegate to an auxiliary those aspects of eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). When other aspects of eye care for which the ophthalmologist is responsible are delegated to an auxiliary, the auxiliary must be qualified and adequately supervised. An ophthalmologist may make different arrangements for the delegation of eye care in special circumstances, such as emergencies, if the patient's welfare and rights are placed above all other considerations.

8. **Postoperative Care.** The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise, the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist. The operating ophthalmologist may make different arrangements for the provision of those aspects of postoperative eye care within the unique competence of the ophthalmologist in special circumstances, such as emergencies or when no ophthalmologist is available, if the patient's welfare and rights are placed above all other considerations. Fees should reflect postoperative eye care arrangements with advance disclosure to the patient.

9. **Medical and Surgical Procedures.** An ophthalmologist must not misrepresent the service that is performed or the charges made for that service.

10. **Procedures and Materials.** Ophthalmologists should order only those laboratory procedures, optical devices or pharmacological agents that are in the best interest of the patient. Ordering unnecessary procedures or materials for pecuniary gain is unethical.

11. **Commerical Relationships.** An ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally-related commercial enterprises.

12. **Communications to Colleagues.** Communications to colleagues on research including clinical investigation must be accurate and truthful. Appropriate disclosure of commercial interest is required.

13. **Communications to the Public.** Communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information through statements, testimonials, photographs, graphics or other means. They must not omit material information without which the communications would be deceptive. Communications must not appeal to an individual's anxiety in an excessive or unfair way; and they must not create unjustified expectations of results. If communications refer to benefits or other attributes of ophthalmic procedures that involve significant risks, realistic assessments of their safety and efficacy must also be included, as well as the availability of alternatives and, where necessary to avoid deception, descriptions and/or assessments of the benefits or other attributes of those alternatives. Communications must not misrepresent an ophthalmologist's credentials, training, experience or ability, and must not contain material claims of superiority that cannot be substantiated. If a communication results from payment by an ophthalmologist, this must be disclosed unless the nature, format or medium makes it apparent.

C. ADMINISTRATIVE PROCEDURES

The Administrative Procedures form the third part of this Code of Ethics. They provide for the structure and operation of the Ethics Committee; and they detail procedures followed by the Committee and by the Board of Directors of the Academy in handling inquiries or challenges raised under the Rules of Ethics. All ophthalmologists who are Fellows or Members of the Academy in any class of membership are required to comply with these Administrative Procedures; failure to cooperate with the Ethics Committee or the Board of Directors in a proceeding on a challenge may be considered by the Committee and by the Board of Directors according to the same procedures and with the same sanctions as failure to observe the Rules of Ethics.

1. Ethics Committee

a. The Committee. The Board of Directors appoints at least five, but not more than nine, ophthalmologists who are Voting Fellows or Members of the Academy to serve three-year, staggered terms as members of the Ethics Committee. The Board of Directors makes its appointments to the Committee from among respected ophthalmologists who will, to the extent practicable, assure that the Committee's composition is balanced as to relative age and experience and as to the emphasis of the appointees upon practice, education, research or other endeavors within ophthalmology. Members of the Ethics Committee may serve no more than two three-year terms. However, a member appointed as Chairman or Vice Chairman of the Committee may serve no more than three, three-year terms. Members may resign from the Committee at any time. Membership on the Ethics Committee may be terminated by the Board of Directors at any time and for any reason. Vacancies on the Committee are filled by the Board of Directors. Committee members are reimbursed for expenses. The Ethics Committee is responsible for (i) developing and implementing an educational program regarding the Code of Ethics among ophthalmologists and ophthalmologists-in-training who are Fellows or Members of the Academy, (ii) investigating each inquiry regarding ethics and recommending whether the Board of Directors should issue an advisory opinion interpreting the Rules of Ethics in this Code, (iii) investigating each challenge regarding ethics and recommending whether the Board of Directors should make a determination that a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code, and recommending an appropriate sanction, and (iv) assessing the Principles of Ethics, Rules of Ethics and Administrative Procedures in this Code periodically and recommending any amendments to the Board of Directors.

The Chairman of the Committee. Upon nomination by the President-Elect of the Academy, the Board of Directors appoints one member of the Ethics Committee as the Committee's Chairman to serve, at the will of the Board of Directors, as the principal administrative officer responsible for management of the promulgation, interpretation and enforcement of this Code of Ethics. The Board of Directors appoints as the Chairman a distinguished ophthalmologist who possesses recognized integrity and broad experience. The Chairman of the Committee is responsible directly and exclusively to the Board of Directors; the Chairman is reimbursed for expenses and, upon the approval of the Board of Directors, may be paid for services; and the Chairman is provided, upon the approval of the Board of Directors, with staff, legal counsel and other resources necessary to fulfill the responsibilities of administering this Code. The Chairman presides at, and participates in, all meetings and hearings of the Ethics Committee, except at any hearing at which the Committee considers the possible failure of a Fellow or Member of the Academy to observe the Rules of Ethics in this Code. The Chairman is responsible for ensuring that these Administrative Procedures are followed. The Chairman maintains liaison with entities, both public and private, which are interested or involved in medical ethics, particularly as they relate to ophthalmology.

c. The Vice Chairman of the Committee. Upon nomination by the President-Elect of the Academy, the Board of Directors appoints one member of the Committee as the Committee's Vice Chairman to serve, at the will of the Board of Directors, in the place of the Chairman when the Chairman is unable to serve.

d. Meetings of the Committee. Meetings of the Ethics Committee are called upon at least seven days' written notice to Committee members, which notice includes a copy of the agenda for the meeting. A quorum consists of a majority of all of the appointed Committee members. Voting is by majority of those present at a meeting (or by a majority of those submitting votes in a mail vote). Mail voting without a meeting is permitted where all Committee members submit mail votes or abstentions. Voting by proxy is not permitted. A member of the Committee must decline to participate in the consideration of, or the decision in, any matter before the Committee in which the member has a personal interest.

e. Indemnification and Insurance. All Ethics Committee members, staff, and other individuals engaged in investigations at the written request of the Chairman, are indemnified and defended by the Academy against liability arising from Committee-related activities to the extent provided by the Bylaws of the Academy for Directors, Officers, employees and agents. The Academy maintains indemnification insurance against such liability.

2. Inquiries and Challenges

a. Preliminary Review. The Chairman preliminarily reviews each submission involving this Code of Ethics to consider whether it may be an inquiry (i.e., a request for issuance by the Board of Directors of an advisory opinion interpreting the Rules of Ethics in this Code) or a challenge (i.e., a request for a finding by the Board of Directors that a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code). A submission involving this Code of Ethics, whether or not it is designated or phrased as an inquiry or challenge, may be construed by the Chairman or the Committee as either an inquiry or a challenge in the light of information in the submission. Inquiries may be considered without regard to their means or form of submission. Challenges are not considered unless they are submitted in writing and signed by their submitters. Inquiries or challenges may be submitted by ophthalmologists (whether or not they are Fellows or Members of the Academy), other physicians, health care institutions, health care reimbursers, allied health professionals, patients or organizations representing any of these.

b. **Preliminary Disposition.** Upon preliminary review of a submission involving this Code of Ethics, the Chairman may conclude, in the Chairman's sole discretion, that the submission (i) contains insufficient information on which to base an investigation or (ii) is patently frivolous or inconsequential, i.e., it does not present an issue of interpretation of the Rules of Ethics in this Code adequate to constitute a valid and actionable inquiry and to justify bringing the submission before the Committee for investigation and recommendation to the Board of Directors on issuance of an advisory opinion or it does not present an issue of the failure of a Fellow or Member of the Academy to observe the Rules of Ethics in this Code adequate to constitute a valid and actionable challenge and to justify bringing the submission before the Committee for investigation and recommendation to the Board of Directors on a determination of failure to observe the Rules of Ethics. If so, the submission is disposed of by notice from the Chairman to its submitter, if the submitter is identified. Each such preliminary disposition by the Chairman of a submission involving this Code of Ethics is reported to the Ethics Committee.

c. **Investigation.** For each submission involving this Code of Ethics that the Chairman concludes is a valid and actionable inquiry or challenge, the Committee conducts an investigation into its specific facts or circumstances to whatever extent is necessary in order to clarify, expand or corroborate the information provided by the submitter or in order to determine, with respect to a challenge, whether it is most appropriately raised under the Rules of Ethics in this Code and considered further by the Ethics Committee and Board of Directors rather than by some other entity engaged in the administration of law or the regulation of the conduct of physicians, such as a law enforcement agency, physician licensing authority, medical quality review board or professional peer review committee. The Chairman supervises each investigation and may conduct an investigation personally. The Chairman may be assisted in the conducting of an investigation by other Ethics Committee members or by Committee staff. The Chairman may also be assisted by any other individual, such as a member of the Board of Councillors of the Academy (i) whose location, professional position or expertise might facilitate the investigation, (ii) whose assistance is requested in writing by the Committee Chairman, and (iii) who agrees in writing to follow the Administrative Procedures of this Code; but only when all three of those conditions are fulfilled. A Fellow or Member of the Academy who is the subject of a valid and actionable challenge is informed in writing at the beginning of the Committee's investigation as to (i) the nature of the challenge, (ii) the obligation to cooperate fully in the Committee's investigation of the challenge, and (iii) the opportunity to request a hearing on the challenge before the Ethics Committee. Investigations involving challenges are conducted in confidence, with all written communications sealed and marked "Personal and Confidential", and they are conducted objectively, without any indication of prejudgment. An investigation may be directed toward any aspect of an inquiry or challenge which is relevant or potentially relevant.

3. Proceeding on Inquiries

a. Hearing on an Inquiry. In the course of an investigation involving an inquiry, the Committee may conduct a public administrative hearing to receive the views of those who are interested in, or may be affected by, issuance by the Board of Directors of an advisory opinion interpreting the Rules of Ethics in this Code. Thirty days' written notice of the hearing is given to the Fellows and Members of the Academy and to others who, in the opinion of the Committee, may be interested in, or affected by, issuance of an advisory opinion. The notice may include a tentative proposed advisory opinion. The hearing is conducted by the Committee with any three or more Committee members participating. The Chairman of the Committee serves as the Hearing Officer to preside at the hearing and assure that these Administrative Procedures are followed. The Hearing Officer may issue any appropriate procedural or evidentiary ruling in the course of the hearing and may be assisted by legal counsel. The Hearing Officer presents at the hearing the issues raised by the inquiry, the results of the investigation up to the time of the hearing, and any tentative proposed Committee recommendation to the Board of Directors for an advisory opinion. Information is offered through witnesses, who may be assisted by legal counsel and are subject to questioning by the Committee. Any information may be considered which is relevant or potentially relevant. A transcript or recording of the hearing is made. The official record of the hearing becomes part of the investigation of the inquiry.

b. Recommendation on an Inquiry. Upon completion of an investigation involving an inquiry, the Ethics Committee recommends whether the Board of Directors should issue an advisory opinion interpreting the Rules of Ethics in this Code. If the Committee so recommends, a proposed advisory opinion is prepared under the supervision of the Chairman and is submitted to the Board of Directors along with a summary of the record of the Committee's investigation. The Board of Directors has access to the entire record of the investigation. If the Committee recommends against issuance of an advisory opinion, the inquiry is dismissed with notice to its submitter, if the submitter is identified, and a summary report is made to the Board of Directors.

c. Advisory Opinion. The Board of Directors issues an advisory opinion interpreting the Rules of Ethics in this Code (i) upon the recommendation of the Ethics Committee arising from an inquiry and following an investigation or (ii) upon the recommendation of the Committee arising from its own initiative. A representative of the Committee presents to the Board of Directors, for its review, the recommendations of the Committee and its record of the investigation. Once issued by the Board of Directors, the advisory opinion is promulgated by publication to the Fellows and Members of the Academy. Advisory opinions are compiled by the Ethics Committee; and the compilation is periodically made available to the Fellows and Members of the Academy.

4. Proceedings on Challenges

a. **Hearing on a Challenge.** In the course of an investigation involving a challenge, the Committee conducts a private adjudicative hearing if one is requested by the Fellow or Member of the Academy who is the subject of the challenge or at the Committee's own initiative. Thirty days' written notice of the hearing is given to the Fellow or Member. The hearing is conducted by the Committee with any three or more Committee members participating, other than (i) the Chairman, (ii) any Committee member who assisted substantially in the investigation of the challenge, and (iii) any Committee member whose professional activities are conducted at a location in the approximate area of that of the Fellow or Member of the Academy who is the subject of the challenge. Those Committee members participating in the hearing elect from their number a Hearing Officer to preside at the hearing and assure that these Administrative Procedures are followed. The Hearing Officer may issue any appropriate procedural or evidentiary ruling in the course of the hearing and may be assisted by legal counsel. The Chairman of the Committee presents to the Committee at the hearing the results of the investigation up to the time of the hearing. The Fellow or Member of the Academy who is the subject of the challenge, who may be assisted by legal counsel, may refute the results of the investigation and may offer any exculpatory information. The Chairman and the Fellow or Member may offer information through witnesses, who are subject to cross-examination and questioning by the Committee. Any information may be considered which is relevant or potentially relevant. A transcript or record of the hearing is made. The hearing is closed to all except the Committee, the Chairman, the Fellow or Member of the Academy who is the subject of the challenge, their witnesses and counsel, staff and official reporter. The official record of the hearing becomes a part of the record of the investigation of the challenge.

b. **Recommendation on a Challenge.** Upon completion of an investigation involving a challenge, the Ethics Committee recommends whether the Board of Directors should make a determination that the Fellow or Member of the Academy who is the subject of the challenge has failed to observe the Rules of Ethics in this Code. When the Committee recommends a determination by the Board of Directors of non-observance, the Committee also recommends imposition by the Board of Directors of an appropriate sanction. If the Committee so recommends, a proposed determination with a proposed sanction is prepared under the supervision of the Chairman and is presented by a representative of the Committee to the Board of Directors along with the record of the Committee's investigation. If the Committee recommends against a determination of non-observance, the challenge is dismissed, with notice to the Fellow or Member of the Academy who is the subject of the challenge and to the submitter of the challenge, and a summary report is made to the Board of Directors.

c. **Determination of Non-Observance.** The Board of Directors makes the determination whether a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code and imposes an appropriate sanction upon the recommendation of the Ethics Committee arising from a challenge and following an investigation. The Board of Directors reviews the recommendation of the Committee based upon the record of the investigation. The Board of Directors may accept, reject or modify the Committee's recommendation, either with respect to the determination of non-observance or with respect to the sanction. If the Board of Directors makes a determination of non-observance, this determination and the imposition of a sanction are promulgated by written notice to the affected Fellow or Member of the Academy and to the submitter of the challenge, if the submitter agrees in advance and in writing to maintain in confidence whatever portion of the information is not made public by the Board. Additional publication occurs only to the extent provided in the sanctions themselves. If the Board of Directors does not make a determination of non-observance, the challenge is dismissed, with notice to the affected Fellow or Member and to the submitter of the challenge.

d. **Alternative Disposition.** Before the Committee makes any recommendation to the Board of Directors as to a determination that a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code, the Committee may request that the Board of Directors offer the Fellow or Member an opportunity to submit a written assurance that the possible non-observance has been terminated and will not recur. The decision of the Ethics Committee on whether to request that the Board of Directors extend such an offer is entirely within the Committee's own discretion, based upon its investigation of the challenge and upon its assessment of the nature and severity of the possible non-observance when viewed from the point of view of what is in the best interests of patients of the Fellow or Member of the Academy who is the subject of the challenge. The decision of the Board of Directors whether to subsequently extend such an offer is likewise entirely within the Board's own discretion. If an offer is extended, the Fellow or Member of the Academy must submit the required written assurance within thirty days of receipt of the offer; and the assurance must be submitted in terms that are acceptable to the Board of Directors. If the Board of Directors accepts the assurance, notice is given to the submitter of the challenge, if the submitter agrees in advance and in writing to maintain the information in confidence.

e. **Sanctions.** Any of the following sanctions may be imposed by the Board of Directors upon a Fellow or Member of the Academy who, the Board has determined, has failed to observe the Rules of Ethics in this Code, although the sanction applied must reasonably relate to the nature and severity of the non-observance, focusing upon reformation of the conduct of the Fellow or Member and deterrence of similar conduct by others:

   i. Reprimand to the Fellow or Member of the Academy, with publication of the determination but not the Fellow's or Member's name;

   ii. Suspension of the Fellow or Member from the Academy for a designated period, with publication of the determination and with or without publication (at the discretion of the Board of Directors) of the Fellow's or Member's name; or

   iii. Termination of the Fellow or Member from the Academy, with publication of the determination and of the Fellow's or Member's name.

Fellows or Members of the Academy who are suspended are deprived of all benefits and incidents of membership during the period of suspension, except continued participation in Academy insurance programs. In addition, if the Fellow or Member is suspended with publication of the name or terminated, and, if an appeal, is submitted and it ultimately sustains the determination on which the sanction is based, the Board of Directors may authorize the Ethics Committee to communicate the determination and transfer a summary or the entire record of the proceeding on the challenge to, and at the request of, an entity engaged in the administration of law or the regulation of the conduct of physicians, in a proceeding that relates to the subject matter of the challenge, provided, however, that that entity is a law enforcement agency, physician licensing authority, medical quality review board, professional peer review committee, or similar entity; and the Chairman of the Ethics Committee may appear if requested as a witness to that determination and record. Except in the instance of communication of the determination and transferral of the record, or in the instance of request of the record by the Fellow or Member of the Academy who was the subject of the challenge, the entire record, including the record of any appeal, is sealed by the Ethics Committee and the Board of Directors and no part of it is communicated by the members of the Board of Directors, the members of any appellate body, the members of the Ethics Committee, the staff or any others who assisted in the proceeding on the challenge, to any third parties. Fellows or Members of the Academy who are terminated may not reapply for membership in any class.

f. **Appeal.** Within thirty days of receipt of notice of a determination by the Board of Directors that a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code and of imposition of a sanction, the affected Fellow or Member may submit to the Board in writing a request for an appeal. The Board of

Directors establishes an appellate body consisting of at least three, but not more than five, ophthalmologists who are Voting Fellows or Members of the Academy and who did not participate in the Ethics Committee's investigation or in the Board of Director's determination. The appellate body conducts and completes the appeal within ninety days after receipt of the request for an appeal. The purpose of the appeal is to provide an objective review of the original challenge, the investigation and recommendation of the Ethics Committee, and the determination of the Board of Directors, but not, however, the sanction imposed. The appeal is limited to a review of the Ethics Committee's and Board of Directors' application of the Rules of Ethics in this Code to the facts established in the investigation of the challenge and to a review of the procedures followed to ascertain whether they were consistent with those detailed in these Administrative Procedures. An appeal may not take into consideration any matters not included as part of the record of the Ethics Committee's investigation and the Board of Directors' determination. The appeal consists of a review by the appellate body of the entire record of the proceeding on the challenge and written appellate submissions of the Fellow or Member of the Academy who was the subject of the challenge and of the Board of Directors. Written appellate submissions and any reply submissions may be made by authorized representatives of the Fellow or Member and of the Board of Directors. Submissions are made according to whatever schedule is established by the appellate body. The decision of the appellate body either affirms or overrules the determination of the Board of Directors on non-observance of the Rules of Ethics in this Code by a Fellow or Member of the Academy. The decision does not address the sanction imposed by the Board of Directors. The decision of the appellate body, including a statement of the reasons for the decision, is reported to the Board of Directors. The decision is binding upon the Board of Directors, the Fellow or Member who is the subject of the challenge, the Ethics Committee and all other persons.

g. **Resignation.** If a Fellow or Member of the Academy who is the subject of a challenge resigns from the Academy at any time during the pendency of the proceeding on the challenge, the challenge is dismissed without any further action by the Ethics Committee, the Board of Directors or an appellate body established after an appeal; the entire record is sealed; and the Fellow or Member may not reapply for membership in any class. However, the Board of Directors may authorize the Ethics Committee to communicate the fact and date of resignation, and the fact and general nature of the challenge on which a proceeding was pending at the time of the resignation, to, and at the request of, an entity engaged in the administration of law or the regulation of the conduct of physicians, in a proceeding that relates to the subject matter of the challenge, provided, however, that that entity is a law enforcement agency, physician licensing authority, medical quality review board, professional peer review committee, or similar entity.

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Viewpoint

Ethics in Ophthalmology

A Symposium

JEROME W. BETTMAN, SR., MD, MALCOLM A. McCANNEL, MD,
HOMER E. SMITH, MD, FACS, ROBERT E. CHRISTENSEN, MD,
GEORGE R. BEAUCHAMP, MD, JERALD A. JACOBS, JD, RALPH E. KIRSCH, MD

INTRODUCTION

The Code of Ethics of the American Academy of Ophthalmology was developed in response to numerous requests from our members. In May 1979, the American Academy of Ophthalmology sent a questionnaire to its members to ascertain what was wanted. A number of respondents (more than 100) thought that the Academy must develop ethical standards. The goals and priorities committee placed it high in the ratings of needed Academy programs.

In response to these requests, an Ethics Committee was appointed to develop an appropriate code. A national committee was created with the thought that it should represent different types of ophthalmic practice, as well as different geographic areas, but should be small. A local committee was created because it could meet with little expense to the Academy, and could organize ideas for the national committee to consider, thus reducing the need and expense of many national meetings.

The members of the committees are in this symposium, with the exceptions of Drs. Byron Demorest, Morton Goldberg, and Theodore Steinberg, who were not able to participate.

It was evident that standards of ethical conduct varied with the individual. A consensus which represented the standards of ethics of the membership of the American Academy of Ophthalmology had to be developed. The proposed code was discussed at numerous meetings, including a symposium at the 1981 American Academy of Ophthalmology meeting. Comments and opinions from the membership were sought and obtained. Many others were mailed to us. Each comment was carefully considered and the code was modified to respond to those ideas that the committee judged to be desirable. Thus, we developed a Code of Ethics that was the Academy's Code of Ethics and reflected the opinions of a consensus of the membership.

A study of history has made it obvious that a code of ethics must contain sanctions for violators if it is to be effective. There never was, and never will be, a desire to be punitive, but neither do we wish that the Academy should be impotent in regard to ethical standards. To protect every member against any possible injustice, the administrative procedures are designed to include many more safeguards of the right of due process than is required or generally contained in comparable codes.

It is essential that our actions not be interpreted as being in restraint of trade. Therefore, we have worked with the Federal Trade Commission for more than two years to obtain an "advisory opinion". Such an advisory opinion implies an acceptance of our code by the commission, and should shield our Academy from action by that body, and effectively shield it from most legal actions. This advisory opinion was obtained on June 17, 1983.

It was essential that a majority of the Academy's membership approve of this developing code. A copy was sent to every member in 1982. A ballot was also sent to the membership to determine if they approved of the code. Of the entire membership, 3906 (32%) responded, and of this number 94% approved. Only 6% dissented! Some of those who did not approve stated their reasons. The code was modified to respond to those suggestions that seemed acceptable. These included restraints on the power of the chairman to dismiss a challenge that was thought to be frivolous, an appeals committee appointed in advance with tenure, so that it could not be under the control of the Board of Directors, as well as rules concerning

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Reprint requests to Jerome W. Bettman, MD, 3910 Sand Hill Road, Woodside, CA 94062.

postoperative care, and the delegation of ophthalmological services.

In this way, we have created a Code of Ethics in response to the wishes of the membership of the Academy. It reflects the standards of ethics of the membership. It aims to be inspirational, not punitive. However, it contains sanctions which can be invoked when necessary, but only after extraordinary right of due process.

There are some who think that we should not have a Code of Ethics, that nothing should be done to address the numerous significant problems that confront us. These are in the small minority. There are others that believe our efforts will be ineffectual. We have no illusions, there will always be some transgressors who will not be restricted by the code, but without this code our Academy would be impotent.

The code has been developed in accordance with the desires of the membership but within the constraints of the law and the Federal Trade Commission. It was created in accordance with the highest democratic principles: the rule of the majority, but with due regard for the wishes and needs of the minority.

The members of the committee will present the several aspects of the code that evolved after four and one-half years of work.

JEROME W. BETTMAN, SR., MD

FACTORS THAT PRODUCE OR INFLUENCE ETHICAL PROBLEMS

There was a time when a fledgling graduate ophthalmologist needed only a small black bag with a good trial lens set, trial frame, foreign body spud, a bottle of cycloplegic and anesthesia drops, and a well sharpened von Graefe knife. His chief preoccupation was to be sure that when he did his first cataract corneal section to remember not to put the von Graefe knife in upside down. Now all that seems to be changed. Ethical problems, which we hoped would be solved by the Hippocratic oath we took as we graduated and in the old truths which were interpreted by Maimonides' code, are inadequate in today's society where there are many complicating factors which do not easily lend themselves to a simplistic view of the ethical problems confronting all of us. Health professions have faced ethical dilemmas for centuries. With the quickening pace of technological developments, new dimensions of ethics arise.

The chief of a renowned ophthalmology department recently reported to me, after some rather intricate surgery was done on him, that he had four consultant doctor technicians on his case and one honest-to-goodness physician. That should tell us something about the complexities of the highly developed mechanical aids now used by almost all specialists. However, we must guard against being such superb facile technicians with our gadgets that we lose sight of the art of medicine.

When I had my own intraocular lens done three years ago, you can bet that I wanted the best pair of hands that I knew of touching my sacred eyeball, but I also wanted to get somebody who treated me as a whole carcass and not as a quarter-sized sphere with a cataract in it.

HIGH TECHNOLOGY

In the last few years, high technology has developed overwhelmingly in ophthalmic practice. We now have new techniques, diagnostic procedures, and sophisticated surgical modes, approaching our command which certainly improve the quality of care, with a concomitant glamour and appeal, providing plenty of ego food for the ophthalmic surgeon. The fee, which this high expertise commands, is also very much a part of our professional patterns of practice.

Thus, technological changes have introduced new dimensions of the age old problems of the healing professions. To understand problems of ethics, theologians, lawyers, philosophers, and ethicists all contribute their ideas regarding identification and solutions to the moral and ethical questions created by these scientific and technological advances.

SPECIALIZATION

There are many more ophthalmologists being trained today. In addition, many more subspecialists in ophthalmology are being turned out following a specialized fellowship. Most of us, I think, when we finished our medical training and took the Hippocratic oath, had enough ideals and ethics to last us for a lifetime, or so we thought. This blithe unconcern may well have been too pat. Now there is a growing concern that teaching and training programs especially should reemphasize in some way the precepts of ethical and moral behavior patterns and inculcate responsible, caring, supportive behavior patterns to our young trainees in ophthalmology.

In the multispecialty clinics and in the group practices which have developed, we have an intricate interassociation with colleagues who share other specialty interests, and we ask them for consultation and guidance. Medical etiquette overtly enters into this sort of an arrangement. Most ophthalmologists feel that they cannot be competent in all aspects of ophthalmology. This being undoubtedly true, how can we teach our younger practitioners not to feel threatened or inadequate when they should utilize a more informed and experienced consultant in an area of ophthalmology with which they lack familiarity?

The old dichotomies of town and gown, and the responsibilities of busy private practitioners, some of whom have clinical teaching appointments, may make the congenial practice of ophthalmology difficult to achieve. Those who overemphasize their surgical dexterity and their technical competence sometimes lose sight of the fact that the average patient needs or appreciates a great deal of tender loving care, reassurance, compassion, and understanding in addition to inserting an intraocular lens in perfect position or cutting away a third of a hazy vitreous to allow a better view for laser therapy. There was a time when there were no itinerant, qualified ophthalmologists practicing ophthalmology outside the major medical centers and large cities. Now we find very well trained, competent ophthalmologists doing very first class work throughout the countryside.

ADVERTISING

Advertising is now a way of life in many parts of the country and has legal support. Advertising is no longer a justified cause for dismissal from a hospital staff, medical society or licensing. Some older doctors, who have been practicing for years and consider themselves as belonging to the "old school", find it very difficult to utilize comfortably media hype and other communication exposures as a means of getting their message out to potential patients. The complimentary phrase "he is a doctor's doctor" does not seem to be heard as much anymore. All of us use word-of-mouth loyal patients to enhance recruitment of patients, but many find it repugnant and distasteful to gain notoriety by such obvious means as the news media, TV, and radio. True, it may be legal according to law, but we do not have to like it.

THE FEDERAL TRADE COMMISSION

We now find that it is not an easy matter to deal with the fellow practitioner who does things which do not fit in with what has been considered conventional, ethical, proper practice behavior. The Federal Trade Commission has made it very clear that we cannot employ restraint of trade; yet we cannot stand silently by while others use misleading advertising, employ deceptive types of public exposure, and even utilize public relations firms to do so. A conscientious practitioner of the healing arts finds it increasingly difficult to live with this state of affairs without some type of a dismayed, disgruntled murmur.

LITIGATION

Litigation and contention about diagnosis, proper treatment, justified surgery, and follow-up care are increasing. The public now has very high expectations of physicians for the solving of any medical problems. Unknowledgeable, forceful statements concerning end results can hamper efficient convalescence. Many ethical questions are now being raised as to what is proper and suitable care. Any result less than perfect to the patient's, or his lawyer's, eye often demands a great deal of explanation, especially when the lawyer's contingency fee requires no responsibility on his part other than the short letter which he must write to raise the question of impropriety. If there is a question concerning conventional postoperative cataract follow-up, for instance, the surgeon sometimes may be subjected to a lot of needless, repeated recriminations, requiring defensive explanations, such as when the geriatric patient is not able to cope with the reality of unlooked for situations.

Ethical problems arise in the postoperative recovery period, especially if the patient lives some distance from the operating surgeon. Herein one includes etiquette within the field of professional ethics. If our patient returns to his home town nursing facility and faces another colleague, ophthalmologist or otherwise, who is unaware of what the first doctor felt was properand correct treatment, the patient's confidence in the surgeon can be eroded by a maladroit follow-up physician. Hopefully, serious problems are becoming more rare, but when they do occur, the ethics and expertise of an experienced decision-maker is needed, not an overzealous, garrulous colleague who can start fires but is ill equipped to put them out. Proper ethics and professional courtesy demand that postoperative arrangements should be made prior to the surgery. The consulting surgeon should give explanations about the routine care which the follow-up doctor will use, and should be sure that the patient understands and agrees to the plan of treatment.

DRUGS

Medicines which comprised a rather simple pharmacopoeia, thirty years ago, have been modified or replaced by new drugs and new therapy patterns for combatting disease. Nowadays, many non-ophthalmologists are permitted in some states to use ophthalmic drugs for diagnosis and treatment. With so many medicines being used, reactions, allergies, and hypersensitivities can compromise the desired therapeutic result.

Ethical practice of medicine today is not a black-and-white situation, but is perceived to be many shades of gray. An ancient philosopher once said that the important thing in life is not to find the person who knows the answers to the problem, but to find someone who really knows what the problem is. Outside pressures brought on by clinics, spokespersons, hospital boards, media hype, HMO's, group practice, and even solo practitioners make it very difficult for an honest, sincere, well-trained, concerned ophthalmologist to know which way is best to serve his patients.

OPHTHALMOLOGY AS A SPECIALTY

Our specialty lends itself to using paramedical help in gathering data, more so, it seems, than in any other field. To utilize one's time efficiently, we can have our trained staff personnel gather the many bits and pieces of data before the doctor sees the patient. Education and guidance of our staff in proper ethical behavior should be a given. A consultative team approach with the patient and interested family members should work to enhance both the short- and long-range plans for proper treatment. Common sense, fair play, and compassion would seem to be obvious. This is a part of that hallowed doctor-patient relationship which is well known to all of us and is of fundamental importance.

The ethical and moral problems which arise require a course of action based on moral responsibilities and every person's rights. Care should be taken so that moral values will not be preempted by other values. Hopefully, we will possess the inner strength and social skills to implement these worthwhile intentions.

Problems of medical ethics are always with us and will continue to be. We must take stock, think seriously, and emphasize the Golden rule and those aspects of the Hippocratic oath relating to the patient's rights in an up-to-date enlightened relationship with our patients.

MALCOLM A. MCCANNEL, MD

THE EFFORTS OF OTHER ORGANIZATIONS TO DEVELOP AND ENFORCE CODES OF ETHICS

We, as physicians, are not unfamiliar with the historical background of the development of Codes of Ethics. However, we have a concept about the subject as it pertains to our own fields that is more apparent than real. There are those physicians' organizations which function with their own code, and there are those who have a peripheral relationship to a code other than their own.

During the past 15 years there has been an increasing number of codes being promulgated among groups other than physicians. To be sure, they differ from physicians' Codes of Ethics in form and substance, but the principles address the same issues.

NON-MEDICAL

Corporations. Seventy-three percent of the first 1000 corporations listed in FORTUNE magazine reported having a written Code of Ethics. Most of the codes are relatively new, with 50% having been developed since 1975.

Trade Associations. Only 41% of Trade Associations have a written Code of Ethics. One-half of them have had such a code for 25 years. Of the other one-half, 21% have been developed during the past ten years.

Graduate Schools of Business. In the recent past, only 16% of graduate business schools offered specific courses in ethics, in which less than 10% of the students enrolled. An "included" exposure to the subject of ethics was reported in 98% of business schools. A significant change in this attitude was briefly presented in The Wall Street Journal of May 5, 1983. In effect, a Harvard Business School professor stated that business ethics courses are a "growth industry." Further, the article went on to state that a Bentley College survey of 1982 revealed five times as many courses on business ethics are now given as in 1973.

SCIENTIFIC ORGANIZATIONS

The American Association for the Advancement of Science reported on the results of an ethics code survey of its 241 members. Only 178 (74%) of its survey requests responded. In this organization there is a paucity (nine) of medical disciplines in the subdivision of the health care field (which totals twenty-three). This number is not representative of the health care field in general.

PHYSICIANS

The Council of Medical Specialty Societies (CMSS), in 1981, sent a questionnaire to its 24 physician Society members pertaining to their use of a Code of Ethics. The Society responses to questions on Codes of Ethics were: Does your Society have its own Code of Ethics? (yes—seven Societies; no—thirteen Societies); If no, is your Society considering development of its own Code of Ethics? (yes—three Societies; no—ten Societies); does your Society endorse the AMA's Principles of Medical Ethics? (yes—nine Societies; no—seven Societies). The responses from 24 national medical and surgical organizations who were solicited in 1983 as to "the efforts of other medical organizations in developing a Code of Ethics with particular reference to the enforcement provisions" can be grouped into three categories. First, there are seven societies who have their own codes written out and published in their bylaws. A second group, numbering six, specify that they adhere to the "Codes" of the American College of Surgeons or the American Medical Association. The third group of eleven has no code.

ENFORCEMENT

The enforcement of a Code of Ethics is proportional to its viability. This, in turn, is related to the respect for and dedication to the Code by the members of a given organization. it is difficult to determine the extent to which enforcement is pursued, but in seven, at least, the process is firmly in place.

There is a marked similarity in the Codes of these seven. They are the American College of Radiology, American College of Surgeons, American Medical Association, American Society of Plastic and Reconstructive Surgery, American College of Cardiology, American Psychiatric Association, and the American Academy of Dermatology. These codes, as one would expect, conform to the basic legal principles that we espouse. The disciplinary actions consist of:

1. Admonition: a warning or serious rebuke.
2. Censure: a judgement condemning the action as wrong, a reprimand.
3. Probation: a punitive action, for a stated period of time.
4. Suspension: a severe punitive action for a stated or indefinite period of time.
5. Expulsion.
6. Acceptance of resignation "while under investigation."

The American College of Surgeons publishes the disciplinary actions taken by its Board of Regents in *The Bulletin of the American College of Surgeons*. The article lists the date, location by state, offense, and action taken in each instance. No name is listed.

SUMMARY

The interest in the subject of ethics, the development of codes of Ethics, and their enforcement is on the increase. We can take satisfaction with our American Academy of Ophthalmology Code of Ethics as a landmark. You are to be congratulated.

HOMER E. SMITH, MD, FACS

QUESTIONS POSED BY MEMBERS

Many excellent suggestions, submitted in written and verbal forms to the Local and National Academy of Ophthalmology Ethics Committee, were received and considered. All of the submitted ideas and topics were carefully reviewed for possible inclusion in the Code. Therefore, the Committee had the advantage of multiple opinions and inputs from ophthalmologists in different locales, with differing ages, backgrounds, needs, and viewpoints.

The suggestions made by Academy members and the questions asked by them were of great help to the Committee members in their assigned task of formulating the Code. Many of the questions were general enough in scope and specific enough in detail to be included in their submitted form. Others opined about problems too specific for general application to the Academy membership, and may be answered later in advisory opinions. A few remarks and suggestions were self-interested, but the great majority were carefully conceived, clearly worded, and directed toward equitable treatment of the patients and the Academy membership.

It was reassuring to find that the preponderance of topics which interested and concerned the Academy membership were essentially the same ones which occurred to the members of the Academy Ethics Committee in their lengthy deliberations.

Until the Code was completed by the Ethics Committee, adopted by the Board of Directors, approved by the Federal Trade Commission and accepted by the Membership, there was little that could be said in response to member inquiries about the Code. Now, however, some responses can be given, although it must be recognized that comprehensive interpretation of the specific requirements of the Code can only be made through the advisory opinion process provided for in the Code's Administrative Procedures. With that introduction, here are some of the most frequently asked questions about the Code, with preliminary answers.

Question: Does the American Academy of Ophthalmology have the right to institute and enforce a Code of Ethics?
Answer: Yes. Legal decisions provide ample legal precedent for professional associations to promulgate and enforce an effective Code of Ethics. The medical profession in general and Ophthalmology in particular have the right and the responsibility for peer review.

Question: Does the Academy need its own Code of Ethics?
Answer: Yes.

Question: Can't we rely on existing codes from other large organizations?
Answer: No. The Academy needs its own Code of Ethics. Although other legal and ethical tenets already apply to ophthalmologists, there are aspects of the practice of ophthalmology which seem to warrant a specialized code just for that specialty.

Neither state licensing laws, nor Board certification, nor codes of ethics of national or local medical or surgical associations directly address those unique aspects of ophthalmology. The Code provides standards of ethical conduct and behavior for our specialty and was developed in response to requests by the Academy membership. It is intended to apply exclusively to the Fellows and Members of the Academy and does not apply to other health care personnel.

Question: What does "ethics" mean? What is "ethical behavior"?
Answer: The rules of conduct recognized in respect to a particular class of human actions are *medical ethics. Ethical behavior* is that which is professionally right or befitting; conforming to professional standards of conduct.

Question: Can an ophthalmologist be sued for reporting the incompetence of another ophthalmologist?
Answer: Yes, with or without the Academy Code of Ethics. However, many states provide immunity from such prosecution. Some states require the reporting of incompetence. Any self-regulation program of a professional society is essentially selective. However, the Academy has taken extraordinary steps to assure that the likelihood of challenges is minimal and the likelihood of successful challenges is remote. Obviously, obtaining the official approval of the Code by the Federal Trade Commission is one of the most important of those steps.

Question: Does the Academy Code of Ethics provide for due process and proper appeal? Is the Code fair to Academy members?
Answer: Yes. Procedures to carry out the Ethics Rules include full notification of all proceedings, opportunities for a hearing, the right to counsel, the opportunity to cross examine witnesses, and to offer evidence, and the right of appeal. Consistent with due process, procedures include investigation, determination, and appeal by three different objective bodies within the Academy; opportunity for input and argument at each stage of an enforcement proceeding; and opportunity for separate hearing with representation by counsel, if desired. Further, the Academy has made detailed statements regarding ethical ophthalmological conduct, and has published and circulated these for comment.

Question: Is the Code of Ethics immutable, and not subject to change?
Answer: No. The American Academy Code of Ethics is not immutable. It has evolved through extensive discussion, debate and changes over a three-year period. The rules cannot cover every eventuality. Its administrative procedures provide for revisions in the Code of Ethics in Section 8.01, and interpretation of the Code through advisory opinions. Interpretation and modification will be a continuing need.

Question: Is the Code of Ethics strong enough? Does the Code have real "teeth" in it?
Answer: Yes. The American Academy Code of Ethics provides, in economical language, principles of conduct governing the individual and the group. The discipline

of dealing with what is good and bad, and with moral duty and obligation, is provided therein.

The Board of Directors of the Academy views the Code as primarily aspirational and educational in guiding Academy Fellows and Members in their decision-making regarding what is in the best interest of patients. Although its primary role is education and guidance rather than punishment, the Code is regulatory and enforceable. It has real "teeth" in it. Extensive provisions exist for making determinations that individual members of the Academy have violated the Code. Serious sanctions, including suspension or termination of Academy membership, can be imposed. Moreover, in some circumstances, the entire record of an enforcement proceeding can be provided to other entities engaged in legal or ethical enforcement. This is a unique feature of the Academy's Code. Finally, each candidate for membership in the Academy shall agree to, and each Fellow and Member must, comply with the Code of Ethics as a condition of membership or continuing membership in the Academy.

Question: Shouldn't all advertising be banned, and considered cause for sanctions?
Answer: No. The committee is unable to comment on specific ethical inquiries until made, but can only respond broadly and advises that reference be made to Rule 13 on Communications to the Public. The courts have decided that a profession cannot proscribe advertising, although it can regulate false or deceptive advertising. The Code neither encourages nor discourages advertising or communication; it does not prohibit such activities unless they convey false or deceptive information to the recipients of advertising or communications. The Academy's Code is innovative in providing extensive and detailed criteria for evaluating what communications are false or deceptive. In particular, the Code requires affirmative disclosures in certain circumstances, such as when an Academy Fellow or Member publicly discusses the qualitative aspects of a procedure, device, or pharmaceutical.

Question: How do we control surgery or splitting fees or substituting names on operative reports?
Answer: The Code cannot cover every contingency. Some actions mentioned would be illegal and covered by state or local statutes. However, what is legal is not necessarily ethical. Reference should be made to Rule 9 concerning medical and surgical procedures.

Question: Should Academy of Ophthalmology Fellows and Members dispense spectacles, and/or contact lenses?
Answer: The Code does not now address the issue of dispensing. Sometimes dispensing is necessary, and at other times not. There are many difficult issues to deal with when addressing this topic. They can best be handled by advisory opinions on specific issues.

Question: Should third-party payers be specifically involved in the Academy Code of Ethics?
Answer: No. The American Academy Code of Ethics is primarily directed towards the patient and the protection of the patient's interest. If, in the long run, the 3rd party payer is exploited, then the patient is also exploited. There are provisions in the Code relating to fees for ophthalmological services. Academy Fellows and Members are urged in the Code to avoid exploitation of payers through the imposition of fees. Full and fair disclosures of fee arrangements are required, with respect to referred postoperative care situations. Otherwise, the Code does not provide direction on fee or billing practices.

Question: Should the Impaired Physician be included in the Academy Code of Ethics?
Answer: Yes. The recognition and rehabilitation of the Impaired Physician is very important, and may at times relate to ethics. However, the subject cannot be completely covered in a Code of Ethics, and should therefore be addressed by other programs, as it has been in other local, national, and international, organizations.

Question: Should courses unapproved by the Academy of Ophthalmology and those Academy Fellows and Members teaching them be censured by the Academy?
Answer: No. Approval by the American Academy of Ophthalmology of any course would be of benefit to the course sponsor and the course instructors relative to continuing education and recertification credit. However, when the Academy approves a course it is not approving the entire course content nor is the Academy endorsing the course in all aspects. Furthermore, there can be no prohibition of courses unapproved by the Academy, or of participation therein by the Academy Fellows and Members.

Question: What will happen after the Code becomes effective?
Answer: First, there will be widespread promulgation of the Code among Fellows and Members of the Academy through educational and communication endeavors. The Academy has established procedures and is prepared to begin reviewing and acting upon requests for interpretation of the Code and even possible enforcement proceedings. Both endeavors, interpretation or enforcement, must be undertaken carefully and with the utmost regard for the concerns and rights of Academy members and their patients.

Ophthalmologists, by reason of their disciplined education and the orderly nature of their medical training, have reason to know of and to comply with standards of ethical behavior. The American Academy of Ophthalmology membership is to be congratulated for the formulation and acceptance of its Code of Ethics.

ROBERT E. CHRISTENSEN, MD

FEDERAL TRADE COMMISSION ISSUES AND DISCUSSIONS

In 1979, the Academy's Board of Directors, in response to requests from the membership, undertook an investigation of the feasibility of developing an enforceable code of ethics. The sole purpose was to be, and is, to represent and advocate the best interests and welfare of patients. One of the earliest decisions in this effort was to explore the potential legal ramifications, particularly the antitrust issues. The decision was made by the Board in the beginning: the Academy would take a cautious and conservative course in developing and implementing any code of ethics in order to eliminate or minimize potential legal liability.

The Federal Trade Commission (FTC) Act became law in 1915. It prohibits "unfair methods of competition" and "unfair or deceptive acts or practices." Although rarely utilized in recent years, provisions exist for the issuance of Advisory Opinions from the FTC. By this mechanism, the Commission may review a proposed activity prior to implementation. Such an Advisory Opinion may help an organization such as the Academy avoid antitrust enforcement actions involving itself and its members. One reason these opinions have rarely been issued in recent years is that the process can often be difficult. The FTC is a multilayered bureaucracy, with pitfalls at each level: the commissioners are political appointees, subject to individual differences of philosophy which may be reflected in their voting. The staff is divided into three bureaus, with a chief and several layers of staff beneath each. The bureau of competition examines anticompetitive implications; the bureau of consumer protection evaluates consumer deception issues; and the bureau of economics, the economic effects of proposed rules. The staffs of each bureau, at virtually every level, are young attorneys. As a result of this overall structure and composition, the Commission has a tendency—indeed a mission—to evaluate issues exclusively from their legal antitrust viewpoints.

Despite the prospect of potential difficulties, the Academy chose to seek an Advisory Opinion. The purposes were to inform the FTC of the intent of the proposed code of ethics and to avoid language and procedures which would strike obvious (or even subtle) anticompetitive notes with regulators, thereby avoiding possible legal proceedings initiated either by the Commission or individuals seeking protection under federal antitrust statutes. Hopefully the proposed code of ethics of the Academy would not raise issues of anticompetitive restraint.

Once the Academy had drafted a proposed code and obtained comment from members, the FTC process was initiated, at the Board's direction, by legal counsel for the Academy. In 1982, a letter, with the proposed code, was submitted to formally request an Advisory Opinion. A lengthy set of meetings ensued, and communications between the Commission (starting at the lower staff levels) and representatives of the Academy (including ophthalmologists and legal counsel). It is important to remember that FTC staff, trained in the law and particularly sensitive to potential anticompetitive issues, tended to look at the document differently than ophthalmologists. A number of problems and philosophies had to be considered. At times it became clear that the proposed code would have to be changed in minor ways in order to satisfy the FTC of the absence of anticompetitive restraint. Yet it was important that the core elements of the code, ie. those which the Academy members had expressed as crucial to the protection and best interests of their patients, could not and would not be substantively changed. The option remained to withdraw the request without prejudice to further efforts.

As negotiations progressed over some 18 months, it became clear that both sides had to modify their thinking about certain issues. It was also clear that the Academy would have to accept certain language changes if satisfactory FTC opinion was to be achieved. Each contested issue was a case of weighing the benefits of the opinion against the potential disadvantages of the proposed changes. Of the many issues the proposed code addresses, four rules were closely scrutinized by the FTC: (1) clinical experiments and investigative procedures, (2) delegation of services, (3) postoperative care, and (4) communications to the public. These rules, particularly in FTC view, raise the potential issues of restraint of competition (within or outside the profession), restriction of innovation, and suppression of nondeceptive advertising.

The process resulted in changes which preserve the essence of what Academy members consider the basic tenets of ethical behavior. The language in the code is legalistic at times, in order to satisfy the antitrust regulators, but the core of the document is intact.

Additional crosscurrents affected the course of the proceedings. Conceivably, the proposed code could have a minor effect on other professional groups, so a high level of sensitivity to their possible concerns was voiced by the Commission and evidenced by FTC interaction with several groups, including the American Medical Association, general practitioners, optometrists, and others. Further political background to the process was provided by the ongoing concerns of organized medicine as it interfaces with the Commission. An additional bureaucratic delay was made by a change in bureau chiefs toward the end of the process.

On June 17, 1983, the Commission acted. It published its formal advisory opinion. As the first opinion ever issued to a health science organization, the FTC opinion is a milestone. For the Commission, it is the first advisory opinion in FTC's nearly 70-year history which approves without equivocation a self-regulation program of a professional society. In particular, the opinion expresses the first concrete and detailed advice by any legal authority—whether a court or an antitrust enforcement agency—on such important issues as what constitute experimental or investigational medical procedures, and what is false or deceptive advertising by a professional. For the Academy, the FTC opinion is important in that it permits the Academy to proceed with adoption and implementation of the code without excessive anxiety over its potential antitrust implications, and it provides, of course, specific immunity from the FTC.

But care must be taken. The opinion refers only to the language of the proposed code. If it is implemented arbitrarily and/or unfairly, cause for legal action would be available to the FTC and others. Most importantly approval by the FTC was never an end in itself. The Code of Ethics, if enacted, will be an evolving document, clarified by Academy advisory opinions, modified as appropriate, and promulgated through educational programs intended to provide the ultimate end: our patients' best interests and welfare.

GEORGE R. BEAUCHAMP, MD

POINT-BY-POINT ANALYSIS OF THE CODE

It was Montaigne who said, "In polite company, one is often required to learn that which one already knows." Members of the American Academy of Ophthalmology already know what the new Code of Ethics says. The Code has been promulgated in several drafts for the consideration of the membership over the past two years, most recently with a notice of these Academy meetings. However, while the members of the Academy know what the Code says, there undoubtedly remain questions as to what the Code means in specific circumstances arising in the practice of ophthalmology. The Code is comprised of Principals of Ethics, which are aspirational model standards of exemplary professional conduct, of Rules of Ethics, which are enforceable standards of required professional conduct, and of Administrative Procedures, which detail how interpretation and enforcement of the Code will be handled by the Academy. This presentation focuses upon the Code's Rules of Ethics, the enforceable provisions, and reviews them point-by-point with the hope of assisting members of the Academy in understanding how the Rules may apply in practice.

As a preliminary to understanding the Rules of Ethics, four premises of their development are worth noting. First, the Rules are patient-oriented. Every feature of them is designed only to benefit and protect patients of ophthalmologists who are members of the Academy. It is this total and exclusive orientation toward the interests of patients that explains much of what is included in the Rules as well as what has been excluded. Second, the Rules are intended to be primarily educational and only secondarily regulatory. It is expected that all ophthalmologists who are members of the Academy will look to the Rules for guidance in conducting their professional practices. The effect of promulgation of the Rules will in this way likely be widespread and immediate. Only in the presumed rare circumstances of serious nonconformance with the Rules will enforcement be undertaken. The educational role of the Rules has dictated that they be as simple and practical as possible. Third, the Rules are inevitably a legal document. Because they can and will be enforced by the Academy with serious sanctions applied, the Rules have important legal implications. Great effort was taken to assure the absence of anticompetitive ramifications from the Rules, as evidenced by the approval of the Federal Trade Commission. Therefore, no understanding of the Rules is possible without recognition that what is stated in the rules, and how it is stated, has depended to a great extent upon legal requirements, antitrust and otherwise. Fourth, it must be understood that the Rules of Ethics are as yet skeletal. The intention is to develop a body of interpretative material for each of the Rules through formal advisory opinion and enforcement proceedings involving the Code.

For now, an understanding of what the rules *mean* must be based essentially upon what the rules *say*. So far the Academy has begun no advisory opinion or enforcement proceedings under the Code. The only interpretative material that now exists is that drawn from the colloquy between the Academy and the Federal Trade Commission, which resulted in the issuance of the FTC's approval in June 1983. This point-by-point review, then, references the wording of each Rule and includes supplementary comments, when they are available, from the interpretative material in the FTC colloquy.

The preamble to the Rules states that "they are mandatory and directive specific standards of minimally acceptable professional conduct" and that they are "enforceable." It is noted here that the Federal Trade Commission has reviewed and approved the procedures for enforcement of the Rules as legally adequate and not anticompetitive.

Rule 1 is "Competence." The Rule is self-explanatory and as yet has no interpretive material available on it.

Rule 2 is "Informed Consent." It requires the use of "appropriate" informed consent for medical or surgical procedures. The term "appropriate" is key. The Rule recognizes that there are many kinds of informed consents, written or oral, available for use by ophthalmologists. It requires that informed consent procedures be selected which are most appropriate to the circumstances of the patient and of the contemplated treatment. The Rule does not make a specific exception for emergencies. However, that exception is implicit.

Rule 3 is "Clinical Experiments and Investigative Procedures." It requires "adequate review mechanisms" for such experiments or procedures, which are also defined in the Rule. The purpose of the Rule is to safeguard patients by protecting them from uncontrolled experimentation or investigation without restricting innovation. Two important questions raised by the Rule, which must largely await further interpretation by the Academy, are how one defines "clinical experiment or investigative procedure" as well as "adequate review mechanisms." On the first point, the definition in the Rule should be helpful. Essentially, determination of whether a procedure is subject to this Rule, in the absence of a binding determination by an entity in authority such as a hospital board or government agency, depends upon the extent to which reliable information regarding the procedure is available. As to what are adequate review mechanisms, the Rule does not require the use of a local investigational review committee in every circumstance covered by the Rule. For example, the one-time administration of an investigational drug or device to a patient in acute need of the therapy might mandate bypassing an institutional committee review. Yet it is clear an ophthalmologist has an ethical obligation to seek some review, if only through a telephone conference with a colleague, before undertaking a truly experimental or investigative procedure.

Rule 4 is "Other Opinions." It is self-explanatory and has no interpretive material.

Rule 5 is "The Impaired Ophthalmologist." It requires that an impaired ophthalmologist withdraw from those aspects of practice affected by the impairment. If not, other ophthalmologists who know of the impairment are required to take action to assure that withdrawal. The premise of the Rule is that an impaired ophthalmologist may harm patients. Patient protection requires that the ophthalmologist withdraw or be withdrawn from practice.

Rule 6 is "Preoperative Assessment." It is self-explanatory.

Rule 7 is "Delegation of Services." It is intended to declare, in the interest of patient protection, that eye care functions which are unique to the ophthalmologist must ordinarily be performed only by an ophthalmologist and that, when other aspects of eye care are delegated by an ophthalmologist to a non-physician auxiliary, the auxiliary must be qualified and supervised.

The ophthalmologist has already been distinguished in the Code from other health care personnel by virtue of singular education and training. In this Rule on delegation, the Academy has now carried forward the distinction by focusing upon "those aspects of eye care within the unique competence of the ophthalmologist.

However, in addition to eye care functions "within the unique competence of the ophthalmologist," an ophthalmologist is often responsible to the patient for the performance of other aspects of eye care. Furthermore, if and while they maintain responsibility for these other aspects, ophthalmologists routinely choose either to perform the other aspects of eye care themselves or to delegate them to other qualified, supervised health care personnel. Included among the other aspects of eye care that may not ordinarily be within the "unique competence of the ophthalmologist" are patient history review, visual acuity testing, refractions, visual field determinations, measurement of eye pressure, nursing care and other functions. "Other aspects of eye care" are, depending upon the circumstances, performed by such non-physician health care personnel as nurses, technicians, orthoptists, optometrists, technologists, and others. While some of these can and do perform eye care functions independently, they may be termed "auxiliaries" when, and to the extent that, they are performing delegated functions that remain the responsibility of others such as ophthalmologists. The Academy's rule on delegation clearly states its meaning: to the extent that, and for as long as, an ophthalmologist is responsible for other aspects of eye care beyond those within the unique competence of the ophthalmologist, those "other aspects" may be delegated to health care personnel who are qualified and adequately supervised.

The American Academy of Ophthalmology is not a regulator of the scope of practice of health care personnel. Any determination of which precise eye care functions are "within the unique competence of the ophthalmologist" and which functions are "other aspects of eye care" must depend upon factual inquiry into the circumstances of each situation, as well as legal inquiry into whatever governing mandatory or voluntary credentialing mechanisms or authority might exist. One criterion of eye care functions which is obviously not "within the unique competence of the ophthalmologist" is the existence of laws permitting non-ophthalmologists to perform those functions. This criterion is referenced in a parenthetical in the Rule. It states that those aspects of eye care permitted by law to be performed by others are not within the unique competence of the ophthalmologist. Similarly, determination of the precise level of supervision minimally necessary, in delegation of functions for which the delegating individual is responsible, must also be made by reference to the pertinent facts and any applicable law.

Working decisions on these issues are routinely made by practicing ophthalmologists. And, as with any ethical tenet, nonroutine emergency or other such circumstances may justify special responses. The last sentence of the proposed rule on delegation envisions such possibilities, and mandates the patient welfare and rights as the foremost considerations. The sentence clarifies the intent that this Rule be interpreted neither as an unqualified ban on appropriate delegation of services nor as a license for unlimited delegation.

Rule 8 is "Postoperative Care." Essentially, it requires that the operating surgeon should provide postoperative care until the patient has recovered; where an ophthalmologist performs surgery and cannot attend the patient postoperatively, he or she must arrange in advance for the postoperative care with another ophthalmologist; the patient must approve the arrangement; and fees must reflect the arrangement.

The Rule makes clear that it deals only with the performance of "postoperative eye care within the unique competence of the ophthalmologist." Just as in the previous Rule on delegation, this Rule requires that those aspects of postoperative eye care be performed by an ophthalmologist, with the stated preference that it be the operating ophthalmologist who performs the services, since this is ordinarily in the best interest of the patient. From an ethical point of view, as well as from a medical point of view, the patient's best interest is almost always served when it is the original, attending, operating surgeon who handles the follow-up after surgery. Nevertheless, the Rule leaves the operating ophthalmologist free to refer a patient to another ophthalmologist for postoperative care.

Of course, emergency circumstances may arise, or those in which no ophthalmologist is available in the geographic locale of the patient to perform postoperative eye care on a referral basis. The last sentence of the postoperative care rule is specifically intended to cover emergency or other such situations. It establishes the patient's welfare and rights as the ultimate determinants in questions involving postoperative eye care.

In addition, there are certain instances of minor ophthalmological surgery which do not involve extraordinary risks to patients, and for which non-ophthalmologist physicians can and do routinely perform postoperative eye care. They include chalazions, hordeolums, rasions and superficial lacerations on the eyeball or deeper lacerations on the lid, etc. Also, it is not unusual or inappropriate for a preliminary eye care diagnosis of a patient to be performed by a non-ophthalmologist medical doctor, such as in larger clinics. The language of Rule 8 envisions that non-ophthalmologist physicians with appropriate training and experience are not to be precluded from performing such postoperative care, since the rule limits itself to aspects of postoperative eye care "within the unique competence of the ophthalmologist," and since it requires that the patient's welfare and rights be placed above all other considerations.

Rule 8 involves only postoperative eye care that is performed by physicians. It does not affect the ability of ophthalmologists to delegate certain aspects of eye care for postoperative patients to qualified and supervised auxiliaries in accordance with Rule 7.

In summary, Rule 8 reflects that (1) postoperative eye care should preferably be the responsibility of the ophthalmologist performing the surgery whenever possible; (2) when the ophthalmologist performing the surgery cannot provide postoperative care, it is in the patient's best interest for another ophthalmologist to provide that postoperative care; and (3) referral of postoperative care by the operating ophthalmologist to another ophthalmologist should be done only when necessary, and when approved in advance by the patient and by the other ophthalmologist who will perform the postoperative care, nd the financial arrangements should also be made clear to the patient in advance.

Rule 9 is **"Medical and Surgical Procedures."** It is self-explanatory.

Rule 10 is **"Procedures and Materials."** It is self-explanatory.

Rule 11 is **"Commercial Relationships."** It requires that clinical judgment and practice remain unaffected by professionally related commercial enterprises. Note that it does not ban those relationships.

Rule 12 is **"Communications to Colleagues."** It is self-explanatory.

Rule 13 is **"Communications to the Public."** It sets out several requirements for advertising and other communications to the public. The Rule focuses upon the need for accurate statements to the public by ophthalmologists who are members of the Academy, regardless of the nature, format, or medium of those statements (ie. promotional or nonpromotional). The Rule bans false or deceptive communications, both affirmative misrepresentations and misrepresentations arising from the failure to disclose a material fact. The requirement on disclosure of material facts does not mandate that every communication be all-inclusive, only that it not omit what is necessary to avoid deception. It does not ban any particular form of communication, such as testimonials or pictorial representations; rather, it provides that these and other forms of communications must not convey false deceptive information.

Rule 13 also prohibits certain specific types of representations. The Rule bans communications that: "appeal to an individual's anxiety in an excessive or unfair way"; "create unjustified expectations of results"; "misrepresent an ophthalmologist's credentials, training, experience or ability"; or "contain material claims of superiority that cannot be substantiated." The Rule places the burden of substantiation upon the initiator of a communication.

Finally, Rule 13 contains two disclosure requirements. Disclosures regarding safety, efficacy, and the availability of alternatives must be made if a communication refers to "benefits or other attributes of ophthalmic procedures or products that involve significant risks," and in some cases descriptions or assessments of alternative treatments must be given. It is minimally necessary, in order to avoid deception, to require disclosure by ophthalmic surgeons who are Academy members of the existence of alternatives when qualitatively describing ophthalmic procedures or products to the public which involve significant risks, and which have alternatives, and to require identification or even description of the alternatives in circumstances in which that information is essential to avoid deception to the public. Separately, a communication must include a disclosure that it "results from payment by an ophthalmologist" when this is the case and it is not obvious from the nature, format, or medium of the communication. Publication of statements to the public, such as about the services of particular ophthalmologists, must bear disclosure that the publication of those statements resulted from payments by the ophthalmologists or their agents, if this is the case, and if it is not apparent from the nature, format, or medium of the statements. Obviously, there are certain statements which will appear from their context to have resulted from the payment of money, ie. a boxed announcement in the Yellow Pages. For those statements where this factor is not obvious (ie. print or broadcast media interviews), any payments must be disclosed.

All of the disclosures identified in the Rule are required only when necessary to avoid deception. For example, mere identification of an ophthalmic procedure or product that involves significant risks, without reference to its benefits or other qualitative attributes, will not trigger the disclosure requirement. Also, an advertisement for routine eye examinations, such as "safeguard your health; get your eyes checked; careful and thorough eye examinations by appointment," would not need to contain the disclosures identified in Rule 13. Finally, the disclosure requirements of the Rule would not be triggered by a communication that advertised the fitting or provision of contact lenses and noted such attributes as improved appearance, user comfort, or inexpensiveness.

This concludes the point-by-point review of the Rules of Ethics based upon the colloquy between the Academy and the FTC. Undoubtedly, many practical questions remain regarding interpretation of the Rules. The Academy intends to begin issuing official interpretations as soon as is practicable.

JERALD A. JACOBS, JD

PROCEDURES REGARDING INQUIRIES AND CHALLENGES

The Bill of Rights of the United States Constitution guarantees United States citizens all the privileges believed due the people of a democratic nation. Similarly, we hope that your Code of Ethics will guarantee each fellow or member all the privileges of a democratic Academy, with careful attention to due process and with diligent protection for the challenged.

PRELIMINARY PROCEDURES

How will these safeguards operate? Any one of us may be the subject of an *inquiry* or a *challenge*. An inquiry is a request for an advisory opinion interpreting the Rules of Ethics, while a challenge is a request for a finding that a fellow or member has failed to observe the Rules of Ethics. Thus, whenever the Ethics Committee receives a submission, the first step will be a preliminary review by the Chairman to determine whether this submission is an inquiry or a challenge. The Chairman also determines preliminarily whether the submission is valid or whether it is inconsequential. All submissions reaching the Committee are investigated by the Committee to determine that the submission is indeed an ethical problem, rather than a legal or regulatory matter. If the problem is one of ethics and is an inquiry, the Committee will pass immediately from preliminary procedures to its definitive procedures. In the case of a challenge, the fellow or member challenged is promptly informed in writing, with an explanation as to the nature of the challenge, his obligation to cooperate and his right to request a hearing.

DEFINITIVE PROCEDURES

Having decided that it will become actively involved in an inquiry or a challenge, the Committee then embarks upon its definitive procedures. In the case of an inquiry, the Committee may hold a public administrative hearing, but first must give 30 days written notice to all fellows and members and to others interested or affected. After this hearing the Committee either recommends to the Board of Directors (along with the Committee's suggestions) that an advisory opinion be issued, or it decides that no advisory opinion is necessary, in which case the inquiry is dismissed, the submitter is notified and a summary of any hearing is sent to the Board.

With respect to definitive procedures involving a challenge, the Committee is charged with the responsibility to investigate in strictest confidence, with all communications sealed and marked "Personal and Confidential." These investigations must be conducted objectively, without any indication of prejudgement. If a hearing is requested by the challenged fellow or member, or by the Ethics Committee, 30 days written notice is sent to the fellow or member, and the date for a private adjudicative committee hearing is set. At the hearing the fellow or member may have legal counsel, he may refute the results of the preliminary investigation, he may offer any exculpatory information he desires, and witnesses may be called.

DETERMINATIONS

At the conclusion of this hearing on a challenge the Committee may make one of two recommendations to the Board of Directors. It may recommend that the Board of Directors shall make a determination that the fellow or member has failed to observe the Rules of Ethics in the Code, and may propose the appropriate sanction. On the other hand, it may recommend against such a determination, in which case the challenge is dismissed, a notice of this decision is sent to both the challenged fellow or member and to the submitter of the challenge, and a summary of the hearing and recommendations is sent to the Board of Directors.

The actual determination that a fellow or member has failed to observe the Rules of Ethics in the Code must be made by the Board of Directors, which also has the authority to impose an appropriate sanction. The Board can accept, reject or modify the Committee's recommendation. If the Board accepts the Committee's recommendation, the Board then sends written notice to the challenged fellow or member of its decision and of its sanction. It sends a similar notice in confidence to the submitter. If the Board disagrees with the Committee, the challenge is dismissed, and written notice is sent to both the fellow or member and to the submitter.

In certain cases of challenge, the Committee will have the authority, under its definitive procedures, to recommend an alternative disposition to the Board. If in the Committee's discretion it is warranted, the Committee may recommend that the Board offer the fellow or member an opportunity to submit written assurance that the possible nonobservance of the Code has terminated and will not recur. If the Board accepts the assurance, the submitter of the challenge is notified, providing that the submitter has agreed in advance, in writing, to maintain the information in confidence.

SANCTIONS

When a fellow or member is found by the Board of Directors to be in nonobservance of the rules of ethics of the Code, the Board may apply any one of three sanctions. It may reprimand the fellow or member with publication of the determination but not the name of the fellow or member; it may suspend the fellow or member from the Academy for a designated period, with publication of the determination and with or without the publication of the name of the fellow or member; or, it may terminate membership of the fellow or member with publication of both the determination and the name of the fellow or member.

APPEAL

A sanctioned fellow or member may, within 30 days of the sanction, submit a written request for an appeal. The appeal is made to an appellate body previously appointed by the Board consisting of three to five voting fellows or members of the Academy who were not involved in any aspect of the investigation or decision making. The purpose of the appeal is to provide an objective review of the challenge, the investigation and recommendation of the Committee, and the determination of the Board, but not to impose a sanction. The decision of the appellate body is reported to the Board, and this decision is binding upon the Board, the challenged fellow or member, the Ethics Committee, and all other persons.

DISCLOSURE

Although proceedings of the Ethics Committee and Board involving the Code of Ethics will ordinarily be conducted in complete confidence, a final decision on challenge (or a resignation by a fellow or member during a challenge) may be reported by the Academy to other governmental or non-governmental bodies engaged in the enforcement of law or ethics when the Academy is requested to do so.

RESIGNATION

The subject of a challenge may resign from the Academy at any time during these proceedings. If he does resign, the challenge is dismissed, the record is sealed, and the fellow or member may not reapply for membership in any class in the Academy.

Finally, it is the hope that your Ethics Committee has promulgated procedures concerning inquiries and challenges that not only offer meticulous application of due process and protection of the challenged, but also safeguard the best interests of all patients of the fellows and members of our Academy.

Ralph E. Kirsch, MD

CONCLUSION

We have encountered many difficult problems in creating the Code of Ethics for the American Academy and we are very aware that there will be difficulties that will be encountered in the future. No matter how difficult, our duty to maintain high levels of ethical conduct must not be abrogated.

We have acquired specialized knowledge about the eye which is greatly superior to that possessed by our patients, the public, or other physicians. Because of this knowledge, we can be most useful to society. However, if an ophthalmologist is irresponsible in applying that knowledge he is potentially able to do great harm. In the process, the public's confidence in ophthalmology will be weakened. Any profession which loses public confidence loses a good measure of its usefulness.

The principle of caveat emptor is unthinkable for a profession such as ours.

Knowledge is the essence. It is incumbent upon all those who know, upon ophthalmology as a whole, to set standards of professional ethics. An act of omission such as overlooking a colleague's wrongdoing can be just as unethical as an act of commission. It is to diminish the incidence of both such acts that this Code has been developed and is presented to you, the members.

Jerome W. Bettman, Sr., MD

ADVISORY OPINION OF THE CODE OF ETHICS

AMERICAN ACADEMY OF OPHTHALMOLOGY

SUBJECT: Postoperative Care. 84-5

ISSUES RAISED:

(1) What are the obligations of the operating ophthalmologist with respect to postoperative care?

(2) May an ophthalmologist properly make arrangements for postoperative care to be performed by a non-ophthalmologist?

APPLICABLE RULE: "Rule 8. Postoperative Care. The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist. The operating ophthalmologist may make different arrangements for the provision of those aspects of postoperative eye care within the unique competence of the ophthalmologist in special circumstances, such as emergencies or when no ophthalmologist is available, if the patient's welfare and rights are placed above all other considerations. Fees should reflect postoperative eye care arrangements with advance disclosure to the patient."

CIRCUMSTANCES OF THE INQUIRY

Dr. Able intends to perform cataract surgery on a patient who lives in Dr. Able's community. The surgery would be performed as an in-patient procedure at a hospital where Dr. Able has privileges. Dr. Able proposes to turn over all postoperative examination and treatment to a younger colleague in clinical practice with Dr. Able. Dr. Able wishes to turn over this responsibility because he has a busy clinical, academic and civic schedule, and because he believes that his young colleague would benefit from the experience.

Dr. Baker has scheduled cataract surgery for a local patient who plans to move to his winter home at Pleasant Springs in another state shortly after the surgery. Dr. Baker plans to provide her patient with a report on the surgery as well as a list of ophthalmologists practicing in the Pleasant Springs area, to assist the patient in arranging for postoperative care.

Dr. Charley has a situation identical to that of Dr. Baker. He knows an excellent general practitioner in Pleasant Springs, and therefore he plans simply to arrange for postoperative care of his patient by this physician.

Dr. Delta has a situation identical to that of Dr. Baker. However, although there are ophthalmologists located in the area of Pleasant Springs, Dr. Delta plans to arrange in advance of surgery for postoperative care to be provided by a relative of his, who is an auxiliary practicing there.

All of these surgeons, Dr. Able, Dr. Baker, Dr. Charley, and Dr. Delta, are concerned about the applicability of Rule 8 of the Academy's Code of Ethics to their actions. All four ophthalmologists are Fellows of the Academy.

RESOLUTION OF THE ISSUES RAISED

Rule 8 addresses those aspects of post-surgical care of the patient which are within the unique competence of the ophthalmologist, and which are therefore "integral to patient management" in completing the surgical/medical process. It does not govern aspects of postoperative care, such as mere refractions and dispensing of spectacles, which persons other than physicians are authorized by applicable law to provide.

The primary goal of Rule 8 is to insure that the patient is adequately served throughout his vulnerable period following surgery. The Rule states as its fundamental principle that the operating ophthalmologist should provide those aspects of postoperative care which are "within the unique competence of the ophthalmologist," i.e. are by law not permitted to be performed by auxiliaries. This "should" is not a categorical imperative; but it does state a preference for continuity of care, absent good reasons for departing from this practice. Medical experience shows that, in general, patients are best served by having post-operative care conducted by the physician who best knows their condition -- the operating surgeon. Reasons for departing from this principle would still have to be consistent with the other Rules of Ethics, such as Rule 11 on Commercial Relationships.

There are, however, valid reasons and circumstances which may warrant a departure from the preferred practice of the operating surgeon providing postoperative care. This is particularly so when referral is made to ophthalmologists or other physicians. As to other physicians, it must be noted that because state statutes generally do not define which procedures may be performed only by particular medical specialists such as ophthalmologists, it may not be apparent which procedures are "within the unique competence of the ophthalmologist" as distinguished from other physicians. There are certain types of minor ophthalmological surgery (such as for chalazion, hordeolum, and superficial laceration) for which non-ophthalmologist physicians routinely can and do perform postoperative care without substantial risks to patients. Rule 8 does not restrict such performance of postoperative care by other physicians, since under state law it would not be "within the unique competence of ophthalmologists". The Academy's Code of Ethics does not define scope of practice; it merely refers to applicable state law and to recognized ethical principles of good medical practice. These principles do, however, constrain the judgment of the ophthalmologist somewhat. For example, an ophthalmologist may refer a patient for postoperative care to another physician -- ophthalmologist or non-ophthalmologist -- only if (s)he believes that physician to be competent and prepared to discharge his/her duty to the patient.

The second key principle embodied in Rule 8 is that if the ophthalmologist cannot personally provide the postoperative care, the ophthalmologist must arrange before surgery for postoperative care to be performed by another qualified professional who is acceptable to the patient. Once again, the Rule establishes a preference -- not an absolute rule -- that such care be provided by another ophthalmologist. Because of the special training and competence of ophthalmologists in medical and surgical care of the eyes, it is usually in the patient's best interests that such care be provided by an ophthalmologist. Here, as in all questions under the Code of Ethics, an issue in doubt should be "resolved by the determination that the best interest of the patient is served" (Principle 1). But in every case (except emergencies) the ophthalmologist must make appropriate arrangements before surgery for any postoperative care which (s)he will not be able to handle. If arrangements which are appropriate and acceptable to the patient cannot be made, then (except in emergencies), the ophthalmologist should not perform the surgery.

The third key principle in Rule 8 is that flexibility is permitted to allow different postoperative care arrangements in emergencies or where no appropriate ophthalmologist is available. Finally, the Rule requires that the patient be informed beforehand of the effect of the postoperative care arrangements on the fees for services.

Turning to the cases presented, Dr. Able's decision whether he or his colleague should perform postoperative care must be made on the basis of what is best for the patient, and not simply on the basis of what suits Dr. Able's personal schedule or his colleague's desires. The Rule does not set up an unrealistic standard. All ophthalmologists must operate in the real world, in which schedules sometimes pose conflicts, unforeseen contingencies arise, and so on. In some circumstances, referral to a competent, younger colleague who can devote immediate time and attention to the case may be preferable to handling of postoperative care by a more expert but overburdened senior ophthalmologist. Rule 8 would not condemn Dr. Able's conduct, so long as his demonstrable primary motivation in not handling the postoperative care is the best interests of the patient. However, if an ophthalmologist routinely and repeatedly undertook surgical responsibility for patients and then referred postoperative care to colleagues, serious questions might well be raised about whether (s)he is pursuing the best interests of patients and whether (s)he is in violation of Rule 8.

The facts presented do not disclose what other steps Dr. Able plans to take to comply with Rule 8, but the Rule clearly requires several further actions. First, the arrangements for postoperative care must be made before surgery. Second, even if postoperative care is to be provided by another professional, Dr. Able's responsibility to the patient continues and he must consult with the other professional to the degree necessary to protect the patient's best interests. Third, the patient must be informed beforehand of the arrangements and must approve them. The elements of informed consent recognized under state law and good medical practice must be satisfied. (See Rule 2, and the discussion in Advisory Opinion 84-1.) The ophthalmologist should disclose to the patient the reasons for referring the patient to another for postoperative care, the qualifications of the professional who will undertake such care, and any impact this referral will have on the fees charged. This requirement of affirmative disclosure is reinforced by Rule 9, which provides that "An ophthalmologist must not misrepresent the service that is performed or the charges made for that service." Finally, if the patient does not approve of the proposed arrangement, the ophthalmologist must make a good faith attempt to suggest alternatives which the patient would approve, including deferring surgery until the operating surgeon could perform postoperative care. The patient, of course, has a correlative duty not to act unreasonably in disapproving successive proposals for postoperative care. However, if no satisfactory arrangements for postoperative care can be made, then (except in emergencies) the ophthalmologist should not perform the surgery.

Dr. Baker, who cannot provide postoperative care herself because the patient is moving to another locality, proposes to discharge her obligation to her patient simply by giving the patient a medical report and a list of ophthalmologists. Dr. Baker's proposed course of action clearly violates Rule 8 of the Code of Ethics. First, because cataract surgery is almost never an emergency procedure, serious questions might be raised as to why Dr. Baker needs to perform the surgery now, rather than waiting until the patient returns and she can conduct proper postoperative care, or as to why it might not be preferable for a Pleasant Springs ophthalmologist to do the surgery. Assuming that question is resolved, it is nevertheless clear that if Dr. Baker proceeds, it is her obligation actively to arrange for postoperative care of the patient by a qualified, competent and willing ophthalmologist in Pleasant Springs. Only if all reasonable efforts to do so prove unavailing, may she invoke the "special circumstances" provision of Rule 8, by arranging for such care by a non-ophthalmologist physician, or if no preferable physician is available and it is appropriate for the particular patient, by an auxiliary. In all cases, however, the ophthalmologist's duty to the patient includes identifying and obtaining the commitment of another qualified professional who will share the postoperative responsibility. Once again, except in medical emergencies, the postoperative care arrangements, including fee arrangements, must be explained to the patient beforehand and approved by the patient.

Moreover, an ophthalmologist must undertake to make the best post-operative care arrangements (as outlined above) for each patient on an individualized basis. (S)he may not make general inquiries and assume that the results are applicable for all patients who may present themselves.

Dr. Charley plans to arrange for postoperative care to be performed by a general practitioner who he knows to be an excellent physician. This is acceptable provided that Dr. Charley has considered fairly whether it might be better for the patient to be cared for by an ophthalmologist, and has concluded that no preferable ophthalmologist is available and that the general practitioner can best meet the patient's needs.

Finally, Dr. Delta proposes that the patient be cared for by Dr. Delta's relative who happens to be an auxiliary in Pleasant Springs. Simply taking this action in the first place would clearly violate Rule B, since Dr. Delta has not placed the patient's rights and welfare above all other considerations, and has made no effort to find an ophthalmologist, or other qualified physician, to care for the patient. This clearly would be preferable for the patient, particularly because of the possibility of medical complications during the postoperative period. However, in unusual circumstances, if Dr. Delta tried and was unable to arrange for postoperative care by an ophthalmologist or other preferable physician, arranging for care by an optometrist could be acceptable if Dr. Delta maintains appropriate communication with the optometrist.

APPROVED BY THE ETHICS COMMITTEE IN MAY, 1984
APPROVED BY THE BOARD OF DIRECTORS IN JUNE, 1984.

ADVISORY OPINION
OF THE CODE OF ETHICS

AMERICAN ACADEMY OF
OPHTHALMOLOGY

SUBJECT: Delegation of Services., 84-3

ISSUES RAISED:
(1) How is it determined which services can properly be delegated and which cannot?
(2) What requirements apply when services are delegated?

APPLICABLE RULE: "Rule 7. Delegation of Services. Delegation is the use of auxiliary health care personnel to provide eye care services for which the ophthalmologist is responsible. An ophthalmologist must not delegate to an auxiliary those aspects of eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). When other aspects of eye care for which the ophthalmologist is responsible are delegated to an auxiliary, the auxiliary must be qualified and adequately supervised. An ophthalmologist may make different arrangements for the delegation of eye care in special circumstances, such as emergencies, if the patient's welfare and rights are placed above all other considerations."

CIRCUMSTANCES OF THE INQUIRY

Dr. Miller, a Fellow of the Academy, has established a private practice in general ophthalmology. She employs, among others, a licensed optometrist and an unlicensed assistant. Dr. Miller uses the services of the optometrist to perform refractions and the assistant to plot visual fields and perform other data-gathering functions. She has personally trained the assistant, and supplemented the training of the optometrist. She supervises the activities of both on a daily basis, and knows both to be competent. In the same building in which Dr. Miller practices, a licensed optician has offices. Dr. Miller has no business relationship with the optician but she has directed patients to the optician (as well as to other opticians) for filling prescriptions for spectacles, with satisfactory results. Dr. Miller wishes to know whether these arrangements are consistent with the Academy's Code of Ethics.

RESOLUTION OF THE ISSUES RAISED

Rule 7 of the Rules of Ethics addresses the professional delegation of duties from ophthalmologists to non-physician, auxiliary, health care personnel such as optometrists, orthoptists, technicians, assistants and nurses. Referral to other physicians, even junior members of a practice group, is not such "delegation" and therefore is governed not by Rule 7 but by other Rules of Ethics.

The first principle embodied in the Rule is that an ophthalmologist remains "responsible" for the eye care services provided by auxiliary personnel under her supervision. Therefore, whatever the degree of appropriate delegation, Dr. Miller remains responsible for the quality of services provided by the optometrist and assistant as part of her practice. It appears from the facts presented that she has trained and does supervise both.

Rule 7 does not mandate a particular mode or degree of proper supervision. Under various state laws, supervision requirements may vary from required direct, on-site supervision, to appropriate standing orders and telephone consultations. An ophthalmologist must comply with such state laws, in addition to the requirement in the Rule that the auxiliary be "qualified and adequately supervised." It appears from the facts presented that the optometrist is licensed, and in the absence of any facts to the contrary, it will be assumed that Dr. Miller has a reasonable basis for believing both auxiliaries to be competent.

Dr. Miller is not responsible for the professional performance of the optician, who is not under her control. Of course, an ophthalmologist should not refer patients to an optician if (s)he believes that the optician does not provide high quality services. But in the case presented, the optician's services have been adequate. Also, relations between ophthalmologists and opticians might, in some cases, be governed by other Rules which do not appear relevant in this case, such as Rule 11, which provides that "An ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from, professionally related commercial enterprises."

The next important issue raised by Rule 7 is the proper scope of services which may be delegated to auxiliaries. The Rule makes clear that it is ethical and appropriate for certain functions to be delegated to auxiliaries, in conformity with state law and the Rules of Ethics. Any services which under applicable state law an auxiliary is licensed to perform are therefore not within "the unique competence of the ophthalmologist" under that state system, and they may properly be delegated to auxiliaries. Under the Rule, an ophthalmologist "must not" delegate to auxiliaries those tasks which are within his/her unique competence. Naturally, since state laws vary, practices on delegation will also vary, and the Rule's reference to the "unique competence of the ophthalmologist" does not preclude this. However, the overriding concern of Rule 7 is to insure the best care for the patient. (See also Principle of Ethics 1, which states that "An issue of ethics in ophthalmology is resolved by the determination that the best interest of the patient is served.") Therefore, an ophthalmologist is not required to delegate at all; (s)he may perform all services himself/herself. Moreover, the fact that a particular service under state law is permitted to be performed by an auxiliary does not require an ophthalmologist to delegate it to particular individual auxiliaries, if doing so would not be in the best interests of a patient. The ophthalmologist may, but need not, delegate services, depending upon his/her discretionary professional judgment about the individual auxiliary's skills, the interests of the patient, and other factors.

Dr. Miller has delegated refractions to the optometrist and visual field plotting to the assistant. Under most if not all state laws, these tasks are not within the "unique competence" of the ophthalmologist and therefore, absent some special local regulation, Dr. Miller is free to delegate such services under adequate supervision. Other tasks which frequently will be permissible to delegate to auxiliaries are taking the patient's history, visual acuity testing, measurement of eye pressure, and nursing care. While some auxiliaries, such as optometrists, perform certain of these functions independently, when they function under the control of an ophthalmologist, they are auxiliaries subject to Rule 7 and its requirement of adequate supervision.

The final sentence of the Rule reflects the recognition that whatever the ideal allocation of eye care functions, emergencies and other special circumstances may require different arrangements. The example posed does not require further elaboration on this issue. However, Dr. Miller would not, for example, fail to conform to the Rule's requirement of "adequate supervision" if in her absence in an emergency and after telephone authorization from Dr. Miller, the office optometrist performed certain functions which (s)he might not customarily perform, provided that Dr. Miller reviews the patient's condition as soon thereafter as is feasible.

APPROVED BY THE ETHICS COMMITTEE IN MAY, 1984
APPROVED BY THE BOARD OF DIRECTORS IN JUNE, 1984

SUBJECT: Fees for Postoperative Care 85-1

ISSUES RAISED: May an ophthalmologist ethically pay a portion of his surgical fee to a referring optometrist as compensation for the optometrist's performing the postoperative refraction and other follow-up care?

APPLICABLE RULES: "Rule 8. Postoperative Care. The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise, the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist. The operating ophthalmologist may make different arrangements for the provision of those aspects of postoperative eye care within the unique competence of the ophthalmologist in special circumstances, such as emergencies or when no ophthalmologist is available, if the patient's welfare and rights are placed above all other considerations. Fees should reflect postoperative eye care arrangements with advance disclosure to the patient."

"Rule 9. Medical and Surgical Procedures. An ophthalmologist must not misrepresent the service that is performed or the charges made for that service."

"Rule 11. Commercial Relationships. An ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally-related commercial enterprises."

OTHER REFERENCES: See Advisory Opinions 84-3 (Delegation of Services) and 84-5 (Postoperative Care).

CIRCUMSTANCES OF THE INQUIRY

Dr. Grant, an ophthalmologist (and Fellow of the Academy) is engaged in private practice, and often receives referrals for eye surgery from optometrists in his area. One of these, Optometrist Dunne, approaches him one day and says in essence the following: "Listen, Grant: You're a good ophthalmologist, and I have observed good results in patients I've sent to you. But there are lots of other good ophthalmologists around here. If you want me to continue sending you patients, I think you ought to share your fee with me. When I send you a cataract surgery patient, you just send me a check for $100 — and I'll do the postoperative care and save you the trouble of seeing the patient. Lots of your colleagues are doing this for me, and it's only fair that you do, too. What do you say?"

Dr. Grant has inquired whether, ethically, he may agree to such an arrangement.

RESOLUTION OF THE ISSUES RAISED

Simply agreeing to this arrangement would clearly and unquestionably violate the Code of Ethics. However, this inquiry implicates several different principles which have varying degrees of acceptability in different contexts. First, invocation of the term "fee-splitting" really does not advance the inquiry either way. Traditionally, fee-splitting refers to sharing of fees with another professional simply for the referral of a patient, without regard to whether any services are actually performed. However, even payments from ophthalmologists to optometrists for referrals where the optometrist does perform some services may raise serious problems. Such payments may well lead to unnecessary referrals, unnecessary costs, and referral to ophthalmologists who may not be qualified to handle particular patients' problems. Also, automatic re-referrals to optometrists would be objectionable for the same reasons and may not be in the best interests of patients. Such payments in exchange for referrals are unethical; indeed, they are illegal under most state laws. Moreover, federal law (42 U.S.C. SEC. 1395nn(b), SEC. 1396h(b)) bars payments of this kind in most circumstances where Medicare or Medicaid funds are involved. Ophthalmologists should consult with legal counsel concerning the legality of arrangements in which such payments may possibly be involved. This Advisory Opinion will discuss only their ethical implications.

In order to avoid unethical (and possibly illegal) payments, Optometrist Dunne may only be paid a fee which, in the local market, would be commensurate with his usual fees for the services Dunne actually performs. If there is any substantial "premium" paid in excess of such usual fees, then obviously a fee has been paid for the act of referral itself.

If Dr. Grant were to write a check to Dr. Dunne every time he receives a referral, he would also violate Rule of Ethics 8 on Postoperative Care. Since "the providing of postoperative eye care until the patient has recovered is integral to patient management," Dr. Grant would be remiss in his duties if he routinely and in advance simply arranged (and paid) for Optometrist Dunne to see the patient, assess his condition, and perform the refraction. Dunne may be able to perform the refraction, but it is the operating surgeon's obligation to examine the patient postoperatively and insure that his medical condition is progressing as well as possible. In accordance with Rule 8, provisions for postoperative care should be made on an individualized basis, in light of what is best for each patient. (See Advisory Opinion 85-5.) A standing arrangement for postoperative care for all patients violates this principle.

Dr. Grant must bear in mind that the existence of such a standing arrangement inherently has the potential for influencing his judgment about whether he, or Optometrist Dunne, or another optometrist, can best serve a particular patient's interests. Since Dr. Grant will be obligated to pay Dunne anyway, Dr. Grant might be reluctant to perform such services himself, or to refer the patient to another ophthalmologist, physician or optometrist. This arrangement thus has the inherent potential to violate Rule of Ethics 11, that "An ophthalmologist's clinical judgment and practice must not be affected by economic relationships." Depending on what is or is not disclosed to the patient, such an arrangement may also violate Rule of Ethics 9, which provides that "An ophthalmologist must not misrepresent the service that is performed or the charges made for that service."

The postoperative refraction is an element of postoperative care that is not "within the unique competence of the ophthalmologist", and accordingly, several arrangements would be ethical under the Code. Dr. Grant may perform this service himself and include the cost in his global surgical fee (which is a common practice). Dr. Grant may reduce his global fee by the cost of the refraction and advise the patient that he can receive the refraction from Dr. Grant, from another ophthalmologist, or from an optometrist. However, in order to insure that the patient (and third party payors) understand exactly who is being paid for what service, and to avoid the appearance of impropriety, except in exceptional circumstances, Dr. Grant should not pay an optometrist for the refraction. Instead, the patient should pay each provider of care for the service actually performed by him/her.

APPROVED BY THE ETHICS COMMITTEE IN JANUARY 1985
APPROVED BY THE BOARD OF DIRECTORS IN FEBRUARY 1985

(11)

THOMAS E. FITZ, M.D., PRESIDENT
HICKORY, N.C.

BRYANT D. PARIS, JR.
EXECUTIVE SECRETARY
SUITE 214, 222 NORTH PERSON ST.
RALEIGH, N.C. 27601
TELEPHONE 833-5321

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From: Bryant D. Paris, Jr., Executive Secretary

To: All Licensed Ophthalmologists

Re: Post-operative Care by Optometrists

At its recent meeting, the Board of Medical Examiners adopted a motion that the following views of the Board be sent to all licensed ophthalmologists in the State of North Carolina.

> It has come to the attention of the Board of Medical Examiners that there are a growing number of situations in North Carolina in which ophthalmologists have entered into arrangements with optometrists whereby the optometrists refer to the ophthalmologists patients for cataract surgery and that following such surgery these patients are then returned by the ophthalmologists to the care of the referring optometrists for post-operative care and following. Because it is the view of the Board that such post-operative care and following constitutes the practice of medicine, the practice of permitting persons who are not licensed to practice medicine in the State of North Carolina to provide such care is specifically disapproved by the Board.

BDPjr:kb/0594K

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Medicare

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January 13, 1986

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Some doctors
problems

Medicare Notice

Prudential

Effective immediately, procedure code W9245** has been assigned for routine follow-up cataract surgery care provided by an optometrist or physician other than the operating surgeon. The operating surgeon will use modifier 54 with the appropriate surgical procedure code. (Example - Surgeon 66984-54-LT - Optometrist W9245-LT.)**

Medicare benefits for the follow-up care will be based on a global allowable, and will be subject to coinsurance and deductible. The surgical allowance will be reduced accordingly. Non-routine follow-up care by the operating surgeon due to complications, etc., will still be considered as part of the global surgery allowable. The fitting and dispensing of glasses will be considered a separate service, as at present.

If surgery on the second eye follows closely enough so that substantial follow-up care for both eyes can be handled concurrently, the claim should be coded W9245-YB. For future reference, if the claim for the first eye has already been submitted, the second claim should show the modifier "YB", and the adjusted charge for the second eye so that the proper benefits for the combined care can be determined accordingly. If follow-up care is resumed and continued by the operating surgeon, the optometrist's fee should be reduced accordingly to reflect only the services actually rendered. The same procedure code should still be used. Claims already in process at this time will be subject to the global allowable limits.

Any existing arrangements whereby the surgeon pays the other provider for the follow-up care should be discontinued at once, as HCFA has indicated that the provider rendering the service should do his own billing in order to avoid the inference of referral for the purpose of earning or splitting a fee, which may constitute a violation of the Anti Fraud and Abuse amendments to the Social Security Act. Failure to use the appropriate codes and modifiers may also be considered misrepresentation and may result in investigation and possible sanction action. The name of the referring or referral provider and the date(s) of surgery should be shown on the respective claim forms. It should be remembered that the beneficiary under this new system will be responsible for coinsurance and deductible payments for the referred follow-up care, and the provider will be expected to bill the patient accordingly.

Providers rendering follow-up care should indicate on the claim form all such dates of service which have occurred up to the time the form is submitted. Subsequent dates of service should be documented in the patient's record for Medicare auditing purposes. A global fee should be submitted. The maximum allowables have been established at $175 for one eye, and $225 for both eyes.

**W9245 Post-operative cataract follow-up care by a physician other than the operating ophthalmologist (Includes all services related to surgical care for 120 days from the date of surgery and the prescription for permanent lens(es) or spectacles)

Modifiers - RT Right eye
LT Left eye
YB Both eyes

RESOLUTION

WHEREAS, it is the established policy of the North Carolina Society of Ophthalmology, Inc. ("Society") that its members maintain high ethical standards; and

WHEREAS, after careful review by this Society, it has been determined that the Principles of Ethics of the American Academy of Ophthalmology [and the American Medical Association] can provide helpful guidance and direction concerning such ethics matters; and

WHEREAS, it is the intent of this Society that an impartial Ethics Committee be created to provide an informal forum for the consideration of ethics matters; THEREFORE, BE IT

RESOLVED, that the Bylaws of the Society be amended as follows:

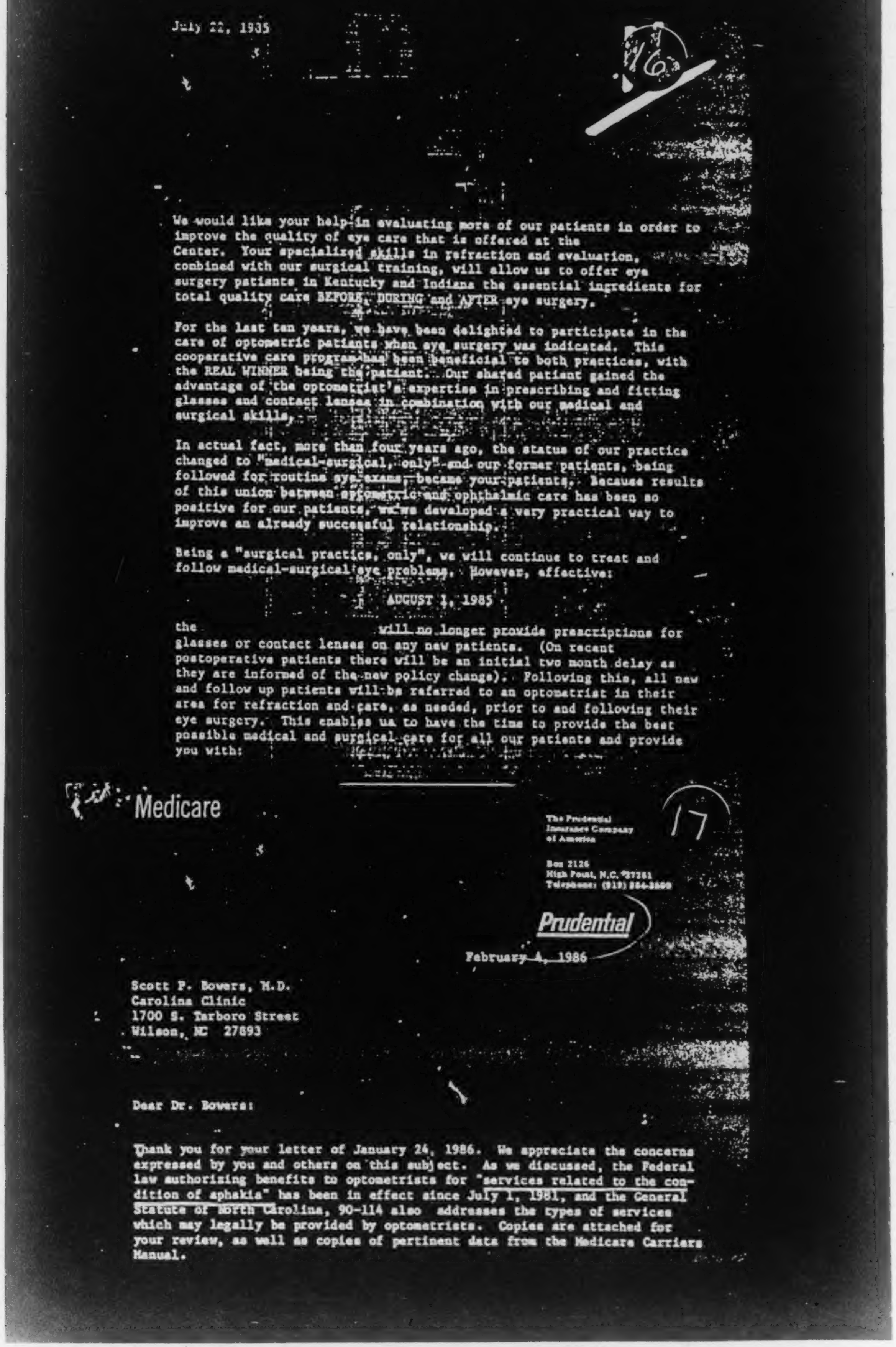
1. Article II, Section 8 of the Bylaws is amended by deleting the last sentence and inserting in lieu thereof the following: "The Principles of the American Academy of Ophthalmology [and the Principles of Medical Ethics of the American Medical Association?] shall guide the conduct of members of the Society and shall be the general standards by which professional conduct is judged, and unethical behavior on the part of a member shall be grounds for expulsion."

2. Article VI of the Bylaws is amended by adding a new Section 2 thereof to read as follows:

"Section 2. Ethics Committee. An Ethics Committee shall be comprised of the current officers and the last five Presidents of the Society and is charged with supervising and mediating matters involving the ethical deportment of its members. The Chairman shall be the current Vice President and legal counsel shall be a consultant to the Committee. The Committee shall review only written and signed complaints against members who practice in North Carolina. The activities of the Committee shall be held confidential, and a member against whom the complaint has been made shall be notified of the nature of the complaint and given an opportunity to respond. All communications shall be considered privileged. The Committee may recommend to complaintants that they submit their complaints to the North Carolina Medical Society, the American Academy of Ophthalmology or the Board of Medical Examiners; further, the Committee may recommend to the Society that membership in the Society be suspended or revoked."

DRAFT 1

B:RESO.TXT



July 22, 1985

16

[redacted]

We would like your help in evaluating more of our patients in order to improve the quality of eye care that is offered at the [redacted] Center. Your specialized skills in refraction and evaluation, combined with our surgical training, will allow us to offer eye surgery patients in Kentucky and Indiana the essential ingredients for total quality care BEFORE, DURING and AFTER eye surgery.

For the last ten years, we have been delighted to participate in the care of optometric patients when eye surgery was indicated. This cooperative care program has been beneficial to both practices, with the REAL WINNER being the patient. Our shared patient gained the advantage of the optometrist's expertise in prescribing and fitting glasses and contact lenses in combination with our medical and surgical skills.

In actual fact, more than four years ago, the status of our practice changed to "medical-surgical, only" and our former patients, being followed for routine eye exams, became your patients. Because results of this union between optometric and ophthalmic care has been so positive for our patients, we've developed a very practical way to improve an already successful relationship.

Being a "surgical practice, only", we will continue to treat and follow medical-surgical eye problems. However, effective:

AUGUST 1, 1985

the [redacted] will no longer provide prescriptions for glasses or contact lenses on any new patients. (On recent postoperative patients there will be an initial two month delay as they are informed of the new policy change). Following this, all new and follow up patients will be referred to an optometrist in their area for refraction and care, as needed, prior to and following their eye surgery. This enables us to have the time to provide the best possible medical and surgical care for all our patients and provide you with:

Medicare

The Prudential
Insurance Company
of America

Box 2126
High Point, N.C. 27261
Telephone: (919) [illegible]

Prudential

17

February 4, 1986

Scott P. Bowers, M.D.
Carolina Clinic
1700 S. Tarboro Street
Wilson, NC 27893

Dear Dr. Bowers:

Thank you for your letter of January 24, 1986. We appreciate the concerns expressed by you and others on this subject. As we discussed, the Federal law authorizing benefits to optometrists for "services related to the condition of aphakia" has been in effect since July 1, 1981, and the General Statute of North Carolina, 90-114 also addresses the types of services which may legally be provided by optometrists. Copies are attached for your review, as well as copies of pertinent data from the Medicare Carriers Manual.

Medicare Bulletin #84-4 was issued from our office, and through subsequent discussions with Health Care Financing Administration, the offering of VCR's etc., as discouraged, and as far as we know was discontinued.

The arrangement whereby payment was to be made by the surgeon to the optometrist was also discussed with HCFA and the Inspector General's office, and they concluded that no impropriety existed as long as a professional service was being rendered. This was the basis for the comments by Mr. Virgil Tuttle of our office in a letter dated September 20, 1984.

Although the comments in Mr. Tuttle's letter may seem inconsistent with the later Bulletin, it stated clearly that providing follow-up visits was the issue, whereas the Bulletin was concerned with referral for a flat fee or opportunity to provide care, which might result in increased cost to the Program, depending on the nature of the offer and the nature of the encouragement. In any event, the arrangement was examined by HCFA and the Inspector General, and they found no basis for action. However, they strongly encouraged billing by the person providing the service, and this was the basis of our January, 1986 instruction after the new coding system was in place and we had obtained approval for the code W9245, and determined an allowable. The modifiers were drawn from Page 346, Appendix A, CPT-Fourth Edition, 1985, published by the American Medical Association.

The action we took was intended to place controls on an existing situation to prevent Medicare paying twice for the same service. We regret that a controversy has developed, but we are following both State and Federal law, and must continue to do so until they are amended, or the State Board of Medical Examiners or Optometry Examiners take licensure revocation action.

Sincerely,

APWalsh

A. P. Walsh, Manager
Office Administration Division

zaa

18A

State of North Carolina
Department of Justice
P.O. BOX 629
RALEIGH
27602-0629

LACY H. THORNBURG
ATTORNEY GENERAL

January 30, 1986

Scott P. Bowers, M.D.
Carolina Clinic, Inc.
1700 S. Tarboro Street
Wilson, North Carolina 27893

Dear Dr. Bowers:

I am writing in response to your recent letter to the Attorney General concerning Medicare policy which appears to authorize fee-spliting between providers. This Office shares your concerns and believes that Medicare should have considered state law before adopting this new policy. The Board of Medical Examiners has an important interest in upholding the ethical standards of the profession which the new policy appears to disregard.

It is hoped that Medicare will heed the opinion of the Board on this matter.

We received the material which you sent to this Office and if it should be helpful to the Board of Medical Examiners, we will forward it to Mr. Bryant Paris.

Very truly yours,

LACY H. THORNBURG
Attorney General

Robert R. Reilly
Assistant Attorney General

RRR:flf

cc:

18B

LACY H. THORNBURG
ATTORNEY GENERAL

State of North Carolina
Department of Justice
P.O. BOX 629
RALEIGH
27602-0629

February 19, 1986

G. W. Riddick, Jr., M.D.
Kinston Eye Clinic, P. A.
Doctors Drive
Kinston Clinic North
Kinston, North Carolina 28501

Dear Dr. Riddick:

I am writing in response to your recent letter concerning the response of this Office to the Medicare policy which appears to authorize fee splitting among providers. We have forwarded all the information received to the Board of Medical Examiners for appropriate action.

The Board of Medical Examiners, by the provisions of Article 1 of the General Statutes Chapter, is authorized to oversee the practice of medicine in this State. G.S. 90-14.12 permits the Board to obtain an injunction against any violation of the statute. Furthermore, G.S. 90-14 provides for the suspension or revocation of the medical license of anyone who engages in prohibited conduct, including failure to conform with the ethics of the medical profession. Only if the Board determines that there may be an unauthorized practice of medicine is the matter referred to the Attorney General for investigation.

If the Board does make a referral to this Office pursuant to G.S. 90-21, this Office will investigate.

Very truly yours,

LACY H. THORNBURG
Attorney General

Robert R. Reilly
Assistant Attorney General

RRR:flf

cc:

19

February 5, 1986

Mr. A. P. Walsh
Manager
Office Administration Division
Medicare - Prudential Insurance Co.
of America
Box 2126
High Point, NC 27261

Dear Mr. Walsh:

I have received your response to the letter and accompanying package of material which was mailed to you last week. Since that initial mailing, I have received responses from various people involved in this issue, and I thought I might share some of them with you. I spoke to Cynthia Rook, the chief legislative lobbyist for the American Academy of Ophthalmology in Washington, D. C. Mrs. Rook related to me the circumstances surrounding the Federal Law authorizing benefits to optometrists. It should be noted that the American Academy of Ophthalmology and the American Optometric Association both sent representatives to the decision makers in HCFA in 1981 to hammer out the limitations and parameters of optometry versus ophthalmology. As quoted by your own letter, benefits to optometrists are for "services related to the condition of aphakia". It was the understanding of both the American Optometric Association and the American Academy of Ophthalmology, at that time, that the words "care" and "postsurgical" would never be applied to the profession of optometry. Optometrists were making noises that they were not being allowed proper reimbursement for refraction and routine services to aphakic patients. Ophthalmology felt that optometrists should indeed be reimbursed for the service of providing refractions to postsurgical patients. The spirit and letter of the rules as they were written and implemented at that time in no way, shape or form intended for optometrists to be allowed to provide postsurgical care. The American Academy of Ophthalmology is shocked and angry that a few selected bureaucrats would take it upon themselves to reinterpret and redefine the rules and regulations which were so carefully hammered out in 1981. Indeed, the Academy intends to fully reopen this issue with the top decision makers in HCFA and find out exactly by whom and when the spirit and intent of the rules and regulations were changed. Again, quoting from your own Medicare carriers manual, section A2020.10 "effective July 1, 1981, expands the coverage of services furnished by optometrists to include services related to the condition of aphakia . . . . . . if the optometrists furnishing these services are legally authorized to perform them". The above carrier's manual excerpt does not list "postsurgical care". I think that organized optometry (with the acquiescence of a few Medicare officials) has taken an inch and stretched it into forty miles. I, therefore, wish to point out to you again that it is the opinion of the N. C. Ophthalmological Society, the N. C. Medical Association, and the Medical Licensing Board of the State of N.C., that you have violated state law. In addition, the American Academy of Ophthalmology feels that the rules and regulations, which were carefully hammered out by optometry, ophthalmology and HCFA, have been re-examined and re-defined to the detriment of organized medicine by a small handful of unscrupulous physicians and providers.

We have notified the attorney general of our displeasure of this state of affairs, and have received notification from his office that "this office shares your concerns and believes that Medicare should have considered state law before adopting this new policy. The Board of Medical Examiners has an important interest in upholding the ethical standards of the profession which the new policy appears to disregard. It is hoped that Medicare will heed the opinion of the Board on this matter."

It seems to me, Mr. Walsh, that a more proper approach to this problem could have been taken by appropriately consulting the Medical Licensing Board of this state and the attorney general's office before placing into effect a policy which has such drastic consequences for the medical profession, and such negative impact on patient care.

It is also disturbing that Medicare seems to have taken no interest in the ethical considerations of such a policy.

It is also interesting that "through subsequent discussion with Health Care Financing Administration, the offering of VCRs, etc. was discouraged, and as far as we know, has continued". I have not been able to locate a single ophthalmologist in the State of N. C. who received any sort of offical or public notice that the offering of VCRs and television sets had been discouraged by HCFA. You and I both know certain ophthalmic practices in the State of N. C. were notified that those schemes were probably in violation of the Medicare Fraud and Abuse Act, and it was in the best interest of those certain practices to discontinue such arrangements immediately. The general perception of organized ophthalmology in this state is that special treatment was singled out for a few large practices. Most ophthalmologists in this state feel that they would have had the various law enforcement agencies on their backs in a heartbeat for such violations, yet a few large practices in this state are "discouraged" from continuing such schemes. There are many ophthalmologists in this state who feel that a case can be made for preferential treatment by government officials towards a few large (and admittedly very profitable) private ophthalmic practices.

Lastly, I am examining the definition of optometry as included in the optometry laws in the N. C. Code. Again, the words "other than surgery" are repeatedly mentioned in the optometric law, and it is obvious that the Legislature of N. C. did not intend for optometrists to endeavor into the realm of surgery or postsurgical management of patients. The N. C. Ophthalmological Society, the N. C. Medical Society, and the N. C. Board of Medical Examiners have indicated their willingness to file suit, if necessary, to obtain whatever legal clarification is needed to resolve this issue once and for all. I might add that Medicare's eagerness to run roughshod over organized medicine, organized ophthalmology, the entire codified body of ethics of the profession, and the N. C. Board of Medical Examiners has not particularly endeared Medicare or the Prudential Life Insurance Company to any of us.

Prudential Life Insurance Company has an excellent reputation in this state, and many physicians are finding it inconceiveable that Prudential would have embarked on such a reckless course without fully exploring the purpose and intent of the Federal Rules and Regulation, the state law, the ethical considerations and the opinion of the Medical Licensing Board and attorney general. I do not think Prudential, Medicare or HCFA has heard the last on this issue as a tremendous groundswell of outrage is developing in this state through both the professional and regulatory bodies to see this unfortunate decision reversed.

Please do not hesitate to call my office at the above listed number if I can provide any further information to you which you may find helpful in regards to this matter.

Most sincerely,

Scott P. Bowers, M.D.

SPB/btb

22a

July 22, 1986

Mr. Bryant D. Paris, Jr.
Executive Secretary
Board of Medical Examiners
State of North Carolina
Suite 214, 222 N. Person Street
Raleigh, NC 27601

Dear Bryant:

The N. C State Ophthalmological Society has recently conducted a practice survey poll of the entire body of licensed ophthalmalogists in the State of North Carolina. It should be noted that this practice survey poll was sent to every licensed ophthalmologist in the state whether or not he was a member of the N. C. Ophthalmological Society. An honest and sincere attempt was made to contact every licensed ophthalmologist, such that the resulting poll would be truly representative of the practice patterns of the ophthalmologists of the State of N. C. I have enclosed a copy of the poll's questions for your perusal. I would like to point out that the poll in no way tries to elicit a certain position from the responders, but simply asks open ended questions in an honest attempt to determine what is the prevailing standard of care in the State of N. C. Four weeks have passed since the poll was first mailed out, and we have now received responses from 143 individuals. This represents a 52% response rate thus far. The results of the poll are as follows:

1. 134 out of 143 ophthalmologists indicated that they did perform some form of cataract surgery for an affirmative response rate of 94%. Nine physicians indicated they did not perform cataract surgery in their practice, and no further information was sought from them from this poll.
2. 130 out of 134 ophthalmologists who perform cataract surgery (97%) indicated that they did perform a history and physical examination on their patients preoperatively. Four individuals (3%) responded that they did not perform a history and physical preoperatively. Of these four responders who did not do preop history and physicals, one wrote that the preoperative history and physical for his patients was always performed by another medical doctor, and a second responder indicated that he did a meticulous history preoperatively on his patients but performed no physical examination.
3. Of those ophthalmologists who performed cataract surgery and performed a preoperative history and physical, 130 out of 130 indicate that they perform this physical examination themselves or have it performed for them by another licensed medical doctor. No physician indicated that they allowed ancillary medical personnel to perform histories and physicals for them. Four physicians left the question blank.
4. 122 out of 134 ophthalmologists indicated that they followed their postoperative cataract surgery patients for eight weeks or longer (91%). Twelve ophthalmologists indicated that they follow their postoperative cataract surgery patients for a period of between five and seven weeks (9%). No ophthalmologist followed their postoperative cataract surgery patients for any less that five to seven weeks.
5. 51 responding ophthalmologists out of 134 who performed cataract surgery indicated that they provided seven or more postoperative visits for their patients (38%). 77 out of these 134 ophthalmologists indicated that they provide between four and six postoperative visits (57.5%). Six ophthalmologists indicated that they provide two to three postoperative visits (4.5%). Combining the first two categories, it is plain that 95.5% of the responding ophthalmologists provide at least four or more postoperative visits to their cataract surgery patients.
6. 126 out of the 134 cataract surgeons responding in this poll indicated that they did perform their own lid block (94%). Eight ophthalmologists (6%) indicated that this function was performed by someone other than themselves.
7. 134 out of 134 of the cataract surgeons who responded to the survey indicaced that they did their own wound closure. No responders indicated that wound closure was performed by anyone other than the operating surgeon.

8. 133 out of 134 (99%) of the cataract surgeons responding to this survey indicated that they did not allow ancillary personnel to provide any of the postoperative follow up examinations for them. One ophthalmologist (1%) indicated that he utilized licensed physicians' assistants to provide postoperative examinations for him.

I believe the information enclosed above is an honest representation of the practice patterns of the ophthalmologists in the State of N. C. An honest attempt was made to poll all ophthalmologists in the State of N. C. whether or not they were members of the various state ophthalmological societies, medical societies or whether they agreed or disagreed with the positions on ethics taken by the various professional organizations. If further responses to this poll are received at a later date we, of course, will update our information and keep you informed about any significant shift in the trend.

I hope this information is helpful to you. Please don't hesitate to call my office at the above listed address and number if I can provide any further information to you which you may find useful.

With best regards, I am,

Sincerely yours,

Scott P. Bowers, M.D.

SPB/btb

Please mail completed survey to:

22B

PRACTICE SURVEY IN NORTH CAROLINA

1. Do you perform cataract extractions with or without implantation of an intraocular lens in your current practice situation? Yes No Please circle one.

2. Do you perform a preoperative history and physical examination on your surgical patients? Yes No Please circle one.

3. If your answer is yes to question #2, are your preoperative examinations performed by yourself, by another MD or by other ancillary personnel? Please specify.

4. How long do you follow your post surgical cataract patients?
   a. one week or less
   b. two to four weeks
   c. five to seven weeks
   d. eight weeks or longer

5. How many postoperative visits do you provide for your patients during their postoperative recovery period?
   a. one or less
   b. two to three
   c. four to six
   d. seven or more

6. Do you do your own regional block if local anesthesia is employed with the surgical procedure? Yes No Please circle one.

7. Do you do your own wound closure at the end of the surgical procedure? Yes No Please circle one.

8. Are your patients followed postoperatively by an optometrist or other ancillary medical personnel (other than for a routine postoperative refraction)? Yes No Please circle one.

Other comments, opinions or suggestions:

23b

January [illegible]

PERSONAL AND CONFIDENTIAL

We are extremely pleased to announce the opening of the 49,000-square foot – [redacted] Center, the largest eye care facility of its kind in the country. The Center encompasses facilities and equipment for comprehensive diagnosis and therapy of all ocular conditions, an operating suite of four totally-equipped operating rooms with complete audio-visual capabilities in each operating room, a 175-seat capacity conference room, as well as many other features.

We are writing to introduce to you the Eye Center, which we plan to develop into a regional eye center with the most experienced eye surgeons available for your patients. In the next several months you will be receiving several communications from us in our attempt to develop with you a cooperative ophthalmic-optometric team approach to provide all of our patients the optimum care available anywhere.

In implementing this regional network, we will soon begin providing you with information on our Professional Referral System, which in accordance with Medicare regulations allows doctors to perform postoperative examinations for a fee. This system will be tailored to your individual desires and practice needs. Continuing medical education seminars and conferences, approved for North Carolina education accreditation will be offered several times during each year, not only addressing eye care problems, but also issues of local, state and national political significance. An affiliation with the Center will also be available to those of you who may be interested, which would allow you to benefit from future public relations and marketing efforts.

The [redacted] will become a regional eye care facility. We will be asking you to join with us in order to guarantee that all of our patients receive the best possible eye care in America.

Sincerely,

24A

THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

Department of Ophthalmology
School of Medicine
(919) 966-5296

The University of North Carolina at Chapel Hill
617 Clinical Sciences Bldg. 229 H
Chapel Hill, N.C. 27514

June 2, 1986

Dear

Thank you for your letter of April 30th. Since I am in the training business, and since I feel strongly about training for postoperative care, I have no problem in expressing my disdain for any surgeon who would let pre- or postoperative care become part of the work of optometrists who are not trained in biology in any special way.

At last month's North Carolina Society of Ophthalmology meeting in Asheville, I pointed out that young physicians having had four years of medical school (after college) are only beginning to get into the biology of surgical care. They take an internship and then spend three or four years in their residency program in ophthalmology. In this situation they have spent approximately eight years more than optometrists in studying disease processes and, especially, the response of the body to injury and disease. Even in that situation, I find that the most difficult of all aspects of the ophthalmology training program is the teaching of postoperative care. There are complications after any ocular surgery that come on quickly, relentlessly and, if not recognized early, may lead to blindness.

It is not particularly difficult to teach someone to become a good ophthalmic cutting surgeon. It is much more difficult to teach them the factors involved with preoperative decision making and postoperative care. From the patient's standpoint it is the total surgical care that counts. It is the height of irresponsibility for any surgeon to allow non-medical personnel to make pre- and postoperative judgements and decisions.

It is up to ophthalmology and ophthalmologists to protect patients from the various short-cuts and schemes that are beginning to appear in this country. Delegating responsibility to non-medical personnel is a short-cut and a scheme, and it behooves all of us to fight these inroads with responsible, knowledgeable, and personal care of all of our patients.

Yours sincerely,

Dave Eifrig
David E. Eifrig, M.D.
Chairman & Professor

Baird S. Grimson
Baird S. Grimson, M.D.
Associate Professor

Kenneth L. Cohen, M.D.
Associate Professor

Susie Y. Wong
Susie Y. Wong, M.D.
Assistant Professor

24B

DUKE UNIVERSITY MEDICAL CENTER

May 5, 1986

Department of Ophthalmology

MEMO TO: Board of Medical Examiners of the State of North Carolina

FROM: Senior Faculty, Department of Ophthalmology

REGARDING: Post-Operative Care by Optometrists

The Department of Ophthalmology of the Duke University Medical Center recognizes the importance of pre- and post-operative care in conjunction with all forms of ocular surgery. While surgical skills are a prerequisite for a favorable surgical result, pre-operative judgement and close post-operative care are equally essential. It is our opinion, therefore, that all three aspects of surgery require the primary attention of an ophthalmologist.

Based on the above considerations, we strongly endorse the position taken by the Board of Medical Examiners of the State of North Carolina of October 4, 1985, which states that the practice of permitting persons who are not licensed to practice medicine in the state of North Carolina to provide post-operative care and following is specifically disapproved by the Board.

Robert Machemer, M.D.
Chairman & Professor of Ophthalmology

W. Banks Anderson, M.D.
Professor of Ophthalmology

Edward G. Buckley, M.D.
Assistant Professor of Ophthalmology

Michael Cobo MD
L. Michael Cobo, M.D.
Assistant Professor of Ophthalmology

Jonathan J. Dutton, M.D., Ph.D.
Assistant Professor of Ophthalmology

Gary N. Foulks, M.D.
Associate Professor of Ophthalmology

Eugene de Juan, Jr., M.D.
Assistant Professor of Ophthalmology

Brooks W. McCuen, M.D.
Associate Professor of Ophthalmology

Calvin H. Mitchell
Calvin H. Mitchell, M.D.
Assistant Clinical Professor of Ophthalmology

M. Bruce Shields, M.D.
Professor of Ophthalmology

James S. Tiedeman, M.D.
Assistant Clinical Professor of Ophthalmology

MBS:rlg

cc:

The Bowman Gray
School of Medicine

WAKE FOREST
UNIVERSITY

Department of Ophthalmology
(919) 748-4091

24c

MEMORANDUM

To: North Carolina Medical Society House of Delegates

From: The Department of Ophthalmology, Bowman Gray School of Medicine,
Wake Forest University

Subject: Medicare Reimbursement of Optometrists for Post-Operative
Cataract Care..

We would like it clearly understood that all of the residents trained in Ophthalmology at this institution are taught that any form of surgery on a patient involves extensive pre-operative evaluation and consultation, the surgical procedure itself, and of equal importance careful post-operative care through the recovery period. There are complications which can follow cataract extraction, which if not identified and treated promptly, can cause significant visual loss or even blindness. We feel very strongly that any follow-up care for a surgical procedure such as a cataract extraction should be performed solely by a medical doctor who has been trained in and experienced all phases of cataract surgery. We strongly endorse the position of the Board of Medical Examiners in reference to post-operative care of patients in the state of North Carolina. We feel strongly that Medicare reimbursement of optometrists for post-operative cataract care should definitely not be allowed.

M. Madison Slusher, M.D.
Chairman & Professor

J. Richard Marion, M.D.
Assistant Professor

Richard G. Weaver
Richard G. Weaver, M.D.
Professor

R. Grey Weaver, Jr., M.D.
Assistant Professor

L. Frank Cashwell
L. Frank Cashwell, M.D.
Assistant Professor

John W. Reid
John W. Reed, M.D.
Associate Professor

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24 D

Medical College of Virginia
Associated Physicians
Department of Ophthalmology
(804) 786-9315

SHAHLA ABEDI, M.D.
JAMES L. COMBS, M.D.
ANDREW P. FERRY, M.D.
SARA A. KALTREIDER, M.D.
ROBERT S. WEINBERG, M.D.

DATE: April 14, 1987

TO: State Board of Medicine
Commonwealth of Virginia

FROM: Department of Ophthalmology
Medical College of Virginia

SUBJECT: Postoperative Care by Non-Physicians

The Department of Ophthalmology of the Medical College of Virginia believes that preoperative and postoperative care is an essential and inseparable part of ophthalmologic surgery. Accurate perioperative examination and management can be provided only by the ocular surgeon, who is qualified to anticipate and treat specific preoperative and postoperative events. Decisions regarding management of inflammation, planning of suture removal to optimize vision, as well as detection of potentially sight-threatening complications of surgery such as endophthalmitis, retinal detachment, or pupillary block glaucoma are all in the realm of the ophthalmologist. The non-physician has no surgical training or experience and can not possibly exercise the judgement and clinical acumen required for even minimal standards of care. Therefore, placing the responsibility of perioperative patient care in the hands of a non-physician is a flagrant violation of the American Academy of Ophthalmology Code of Ethics and presents a danger to the patients' visual health.

We have examined and firmly support the two declarations pending before the State Board of Medicine. We believe these declarations will protect and promote the patients' right to quality care.

Sara A. Kaltreider, M.D.
Sara A. Kaltreider, M.D.
Assistant Professor of Ophthalmology

John B.H. Caldwell, M.D.
John B. Caldwell, M.D.
Assistant Clinical Professor of Ophthalmology

James L. Combs, M.D.
James L. Combs, M.D.
Assistant Professor of Ophthalmology

DuPont Guerry, III, M.D.
Emeritus Professor in Ophthalmology

Walter E. Morgan III
Walter E. Morgan, III, M.D.
Assistant Clinical Professor of
Ophthalmology

Davis B. Wyatt M.D.
Davis B. Wyatt, M.D.
Associate Clinical Professor of
Ophthalmology

John W. Harbison MD
John W. Harbison, M.D.
Professor & Chairman Division of
Neuro-Ophthalmology, Dept. of Neuro

Roderick MacDonald
Roderick MacDonald, M.D.
Clinical Professor in Ophthalmology

Malcolm McGovern MD
Malcolm McGovern, M.D.

Charles J. Blair
Charles J. Blair, M.D.
Associate Clinical Professor in Ophthalmology

Stephen Bernstein, M.D.
Resident, Ophthalmology

Fred Mann
Fred Mann, M.D.
Resident, Ophthalmology

Bill Waschler
Bill Waschler, M.D.
Resident, Ophthalmology

R. K. Buerry, M.D.
Affiliate Assistant Professor of Biomedical Engineering Program
Associate Clinical Professor of Ophthalmology

R. S. Weinberg, M.D.
Associate Professor of Ophthalmology

Parkinson MD
John Parkinson, M.D.
Resident, Ophthalmology

Walter Harris MD
Walter Harris, M.D.
Resident, Ophthalmology

Shahla Abedi M.D.
Shahla Abedi, M.D.
Associate Professor of Ophthalmology

Millicent Palmer, M.D.
Resident, Ophthalmology

Andrew Siedlecki, M.D.
Resident, Ophthalmology

Geoffrey H Cooper MD
Geoffrey Cooper, M.D.
Resident, Ophthalmology

Andrew P. Ferry
Andrew P. Ferry, M.D.
Professor & Chairman Dept. of Ophthalmology

EASTERN VIRGINIA MEDICAL AUTHORITY
1964

EARL R. CROUCH, JR.
CHAIRMAN

EASTERN VIRGINIA GRADUATE SCHOOL OF MEDICINE
DEPARTMENT OF OPHTHALMOLOGY
880 KEMPSVILLE ROAD
NORFOLK, VIRGINIA 23502

TELEPHONE (804) 461-0050

24 E

DATE: April 24, 1987

TO: Members, State Board of Medicine
Commonwealth of Virginia

FROM: Faculty Members
Department of Ophthalmology
Eastern Virginia Medical School

SUBJECT: PRE- AND POST-OPERATIVE OPHTHALMIC CARE

In the Department of Ophthalmology at Eastern Virginia Medical School, we have examined the declarations currently pending before the State Board of Medicine. These declarations seek to guarantee patients undergoing ophthalmic surgery in the state of Virginia appropriate standards of care, both in terms of pre-operative evaluation for surgery and post-operative management.

Evaluating patients pre-operatively and the management of patients post-operatively is integral to the surgical process. Significant complications such as endophthalmitis, wound dehiscence, and filtering blebs could occur when patients are not followed in a responsible manner by their primary ocular surgeon. Abandonment of the patient to auxiliaries following the surgical procedure is not in the best interest of the patients and is a violation of the minimum standards of care.

Earl Crouch
Dr Patrick [illegible], M.D.
William H. Ehlers MD
[illegible] MD.
Leland W. Whitlock MD.
H. B. Taylor Jr MD
R. Thomas Guffey MD

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COMMONWEALTH of VIRGINIA
Department of Health Regulatory Boards
Board of Medicine

BERNARD L. HENDERSON, JR.
DIRECTOR

HILARY H. CONNOR, M.D.
EXECUTIVE DIRECTOR

EUGENIA K. DORSON
BOARD ADMINISTRATOR

1601 ROLLING HILLS DRIVE
RICHMOND, VIRGINIA 23229-5005
[illegible]

1. Do you agree that optometrists should render post-operative care following lens implantation?

   [ ] yes [ ] no

2. If the answer is no, would you say yes provided some specific training was required and verified by a licensing board?

   [ ] yes [ ] no

3. Other than refractions, do you believe optometrists should render any part of post-operative care based on a time interval relative to the date of surgery?

   [ ] yes [ ] no

4. If yes indicate:

   [ ] 1 month
   [ ] 2 months
   [ ] 3 monts

5. Should optometrists be allowed to prescribe or use therapeutic drugs or medicines?

[ ] yes [ ] no

-295 polls mailed
-227 " responses /77% rate
-2/227 ~(79%)
no optom post-op care

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REPORT OF REFERENCE COMMITTEE II
PAGE 4

(7) RESOLUTION 8 - POSTOPERATIVE PATIENT CARE BY PERSONS NOT LICENSED TO PRACTICE MEDICINE IN NORTH CAROLINA

RESOLUTION 21 - POSTOPERATIVE PATIENT CARE BY PERSONS NOT LICENSED TO PRACTICE MEDICINE IN NORTH CAROLINA

RESOLUTION 28 - POSTOPERATIVE CARE OF CATARACT SURGERY PATIENTS

RECOMMENDATION:

Mr. Speaker, Reference Committee II recommends adoption of the following substitute resolution 8 in lieu of Resolutions 8, 21 and 28:

adopted as amended

RESOLVED, That the North Carolina Medical Society agrees with the position that the Board of Medical Examiners of the State of North Carolina has taken stating that the postoperative care of cataract surgery patients constitutes the practice of medicine; and be it further

RESOLVED, That the North Carolina Medical Society seek confirmation through appropriate agencies as to whether permitting persons who are not licensed to practice medicine in the State of North Carolina to provide such care is a violation of the Medical Practice Act; and be it further

RESOLVED, That the North Carolina Medical Society encourage its membership to provide postoperative care in accordance with the ethics of the medical profession; and be it further

RESOLVED, That the North Carolina Medical Society encourage its membership to report to the North Carolina Board of Medical Examiners any violations of the standards of the practice of medicine.

SUBSTITUTE RESOLUTION 8 adopted May 3, 1986 by NCMS House of Delegates

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27A

BEFORE THE BOARD OF MEDICAL EXAMINERS
FOR THE STATE OF NORTH CAROLINA

IN RE:
Respondent

CONSENT ORDER

This cause came to be heard before the Board of Medical Examiners of the State of North Carolina, at hearings held in the months of March, June, July and September, 1987. Evidence was presented concerning several charges and allegations against the Respondent. Petitioner was represented by , and Respondent was represented by The Notice of Charges and Allegations is attached to this Order and incorporated as if set out herein. Prior to conclusion of evidence, the parties have entered into a Stipulation consisting of the following findings of fact:

1. In the treatment of certain patients whose charts are identified in the Notice of Charges and Allegations, , hereinafter ," failed to perform an adequate preoperative examination or physical, in that he delegated to optometrists, nurses, or anesthesiologists the responsibility of performing these functions, prior to cataract surgery. The parties agree that it is not consistent with the standards of acceptable and prevailing medical practices in North Carolina for the surgeon to see a patient for the first time at the time of surgery without having performed a preoperative physical or obtained a preoperative history. agrees that he will thoroughly examine each patient on whom he performs surgery, prior to surgery, and will review the patient's history with that patient. further agrees that he will make an independent diagnosis of cataracts in each patient on whom he performs cataract surgery, and will not rely on others to make that diagnosis. further agrees that he will have a detailed discussion with each patient regarding the diagnosis and the nature of the surgery, advising the patient fully of the risks involved.

2. did not perform the 24-hour postoperative exam following cataract surgery on certain patients whose charts are identified in the Notice of Charges and Allegations. Instead, he delegated such examination to non-physicians, including nurses, and optometrists. The parties agree that delegation of the 24-hour postoperative exam following cataract surgery to non-physicians is not consistent with the standards of acceptable and prevailing medical practices in North Carolina. agrees that he will perform each 24-hour postoperative exam on every patient on whom he performs surgery, with clear documentation that he has performed such examination, except in the case of emergency, in which event, he will ensure that another ophthalmologist performs such exam.

3. did not examine many of the patients whose charts are identified in the Notice of Charges and Allegations at any time after he performed cataract surgery on that patient. This practice is not consistent with the standards of acceptable and prevailing medical practices in North Carolina. agrees that he will provide postoperative care for each patient on whom he performs surgery until the healing process is complete. The parties agree that it is not improper to involve non-physicians in postoperative care, so long as the operating surgeon maintains full responsibility for the patient's postoperative care and examines the patient in the period following surgery to assess the healing process and the long-term results.

4. Appropriately detailed surgical notes describing each patient, his or her condition, the procedures, methods, prostheses, results, prognosis, and medication relative to the surgery, is in the best interests of the patient and should be prepared by or under the direct and immediate supervision of the surgeon. Even in the case of repetitive surgical procedures, a record should be kept of those routine details as well as all significant variations. Some of 's records gave the appearance of being incomplete or unduly duplicative. has modified his record keeping procedures and methods and will henceforth continue to personally prepare separate, detailed surgical notes for each patient on whom he performs surgery.

5. permitted non-physicians to sever sutures on some of those patients whose charts are identified in the Notice of Charges and Allegations. The decision to sever a suture and the act of severing a suture are medical acts. Therefore, the decision to sever a suture should be made by the operating surgeon, and the act of severing a suture must be performed only by the operating surgeon or by those health care practitioners to whom this act may be legally delegated.

6. On several occasions, in the treatment of some patients whose charts are listed in the Notice of Charges and Allegations, allowed non-physicians to sign the prescriptions for medications. It is improper to permit non-physicians to prescribe medicine, except as provided by certain North Carolina General Statutes; one of which is Section 90-114, which permits optometrists to prescribe medicine if there is communication and collaboration with a licensed physician. The Board is of the opinion that communication and collaboration as described in North Carolina General Statutes Section 90-114 requires consultation between the ophthalmologist and optometrist regarding the specific patient for whom the medication is prescribed. In addition, the optometrist should consult with the ophthalmologist on each occasion on which medicine is prescribed. agrees that he will not permit non-physicians to prescribe medicine except as permitted by Statute, and that in those situations described by North Carolina General Statutes Section 90-114, he will consult with the optometrist specifically with regard to the patient for whom medication is to be prescribed.

In consideration of the above finding of facts:

1. The Board of Medical Examiners hereby strongly reprimands with respect to each of the following charges contained in the Notice of Charges and Allegations: 2(a), 2(b), 2(c), 2(d), 2(e), the portion of 2(h) concerning removal of sutures, 3(a), 3(b), 3(c), 3(d), 3(e), 5(a), and the portion of 5(b) concerning removal of sutures;

2. The Board of Medical Examiners hereby dismisses each of the following charges contained in the Notice of Charges and Allegations: 1, 2(f), 2(g), all of 2(h) except the portion concerning removal of sutures, 2(i), 3(f), 3(g), 4, all of 5(b) except the portion concerning removal of sutures;

3. The Board of Medical Examiners will continue to monitor s practice to see that he complies with the requirements of this Order;

4. agrees that he will open his records to agents of the Board at any reasonable time for inspection to assess compliance with the requirements of this Order;

5. will obey all laws;

6. Failure of to comply with this Order shall be grounds, after notice and a hearing, for review, including revocation or suspension of his license to practice medicine.

By order of the Board of Medical Examiners of the State of North Carolina, this the 1st day of October, 1987.

BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NORTH CAROLINA

BY: Charles H. Duckett, M.D.

CONSENTED TO:

PETITIONER, BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NORTH CAROLINA

BY: James L. Blackburn
James L. Blackburn,
Attorney for Petitioner

RESPONDENT,

BY:

BEFORE THE BOARD OF MEDICAL EXAMINERS

OF THE

STATE OF NORTH CAROLINA

IN RE: - [redacted]

NOTICE OF CHARGES
AND ALLEGATIONS

TO: - [redacted]

You are hereby given notice that the Board of Medical Examiners of the State of North Carolina, herein referred to as "Board" has preferred and does hereby prefer against you the following charges and allegations:

1. You represented to the Board that you would be responsible for the supervision of [redacted] and you have failed to supervise adequately and properly [redacted] in that you have failed to countersign patient records for patients upon whom [redacted], performed Blepharopigmentation, also known as eyeliner surgery. Patient records included in this allegation are listed in Exhibit A, attached hereto and are to be identified in the public record as MDM, MSM, MLR, VY, BMK, CF, GJB, SC, AND CAB.

2. In the treatment of your individual patients, hereinafter referred to as "Patients", whose record numbers are separately identified to you in Exhibit B you engaged in unprofessional conduct, including, but not limited to, a departure from, or the failure to conform to, the standards of acceptable and prevailing medical practices in Violation of North Carolina General Statutes section 90-14(a)(6). The violations referred to in this paragraph include the following:

a. As the surgeon you routinely did not perform adequate preoperative examinations or physicals prior to your first meeting with the patient in the [redacted] at which time you administered anesthesia.

b. You routinely neglected to perform the 24 hour exam following closure and instead delegated such examination to non-physicians, including nurses, and optometrists.

c. In many cases you did not examine the patient at any time after the patient left the [redacted] Inc..

d. Surgical notes issued in your name were routinely dictated by someone other than yourself, that person being a non-physician.

e. Your surgical notes are inadequate in that they contain no detail of your findings during operations and are nearly exactly alike for all patient records listed in Exhibit B.

f. You performed unnecessary procedures on patients including but not limited to those whose records are listed in Exhibit C.

g. You gave Timoptic to a patient separately identified to you in Exhibit D, a 68-year-old woman, who you knew or should have known had a long history of respiratory problems.

h. You permitted non-physicians to perform surgical procedures, including YAG Lasar Surgery, Iridectomies, and the removal of sutures on your patients including but not limited to those identified to you in Exhibit E.

i. You presigned blank history and physical forms for patient records including but not limited to those listed in Exhibit F.

3. In the treatment of your individual patients, hereinafter referred to as "Patients", whose record numbers are separately identified to you in Exhibit B you exhibited a lack of professional competence to practice medicine with a reasonable degree of skill and safety for patients in Violation of North Carolina General Statutes section 90-14(a)(11). The violations referred to in this paragraph include the following:

a. As the surgeon you routinely did not perform adequate preoperative examinations or physicals prior to your first meeting with the patient in the Center at which time you administered anesthesia.

b. You routinely neglected to perform the 24 hour exam following closure and instead delegated such examination to non-physicians, including nurses, and optometrists.

c. In many cases you did not examine the patient at anv time after the patient left the

d. Surgical notes issued in your name were routinely dictated by someone other than yourself, that person being a non-physician.

e. Your surgical notes are inadequate in that they contain no detail of your findings during the operation and are nearly exactly alike for all patient records listed in Exhibit B.

f. You performed unnecessary procedures on patients including but not limited to those whose records are listed in Exhibit C.

g. You gave Timoptic to a patient separately identified to you in Exhibit D, a 68-year-old woman, who you knew or should have known had a long history of respiratory problems.

4. You induced patients to consent to unnecessary surgery through false representations to patients in violation of North Carolina General Statutes section 90-14(a)(8).

5. You aided and abetted the performance of medical acts or the practice of medicine by individuals not approved by this Board to perform medical acts in this State nor licensed by this Board to practice medicine in this State in the following:

a. You allowed non-physicians, including nurses and optometrists, to prescribe medicine in your name.

b. You permitted non-physicians to perform surgical procedures including YAG Laser Surgery, Iridectomies and the removal of sutures on your patients including but not limited to those identified to you in Exhibit E.

In the above respects, grounds exist for the revocation of the license to practice medicine issued to you by the undersigned Board.

You are further given notice that you will be given an opportunity to appear before the Board in person and by counsel in a hearing concerning the foregoing charge and allegation on the 10th day of June, 1986, at 9:15 o'clock, AM, at the at which time you may present evidence on your behalf. In the meantime, you may file, within thirty (30) days, a written response to the foregoing charges if you desire.

By order of the Board of Medical Examiners of the State of North Carolina.

This the 7th day of May, 1986.

ATTEST:

Bryant D Paris Jr.
Bryant D. Paris, Jr.
Executive Secretary

MEDICAL EXAMINERS OF
THE STATE OF NORTH CAROLINA

By: Jack A. Koontz M.D.
Jack A. Koontz, M.D.
President

As I See It

This was in the Sept. 87 Issue of Bull. Amer. Col. Surgeons, 72:9, Ed.
Thought you may want to include it in your collection.

The American College of Surgeons has long voiced strong opposition to the practice of itinerant surgery. The fundamental characteristic of an itinerant surgeon is that he or she does not personally perform the diagnostic workup and/or the postoperative care of the surgical patient. An itinerant surgeon is simply an individual who performs the operation, leaves the hospital once the patient is out of the operating room, and usually delegates subsequent care to nonsurgeons who are not fully trained in postoperative management of the surgical patient.

It goes without saying that there are times when very specific clinical skills are required—a situation that allows a particular surgical specialist to perform a specific operation and to delegate the postoperative care to other surgeons who routinely manage the postoperative care of surgical patients. However, these exceptional situations are infrequent.

A rather interesting new development in the itinerant surgery issue recently surfaced when, as reported in the June 1987 issue of *Medical Staff News*, the Board of Trustees of the American Hospital Association (AHA) instructed the staff of the AHA to document "that adequate quality of care standards related to itinerant surgery are being maintained." This charge is particularly interesting in light of the fact that there are no formal guidelines that can be used to evaluate so-called itinerant surgery, other than to compare the results of itinerant surgery with those of ethical surgery.

If one were to play Devil's Advocate, one might ask why itinerant surgery has become of interest to the American Hospital Association. Clearly, there is a downswing in inpatient surgery these days. And, hospitals are under considerable pressure to maintain their financial stability, or even to survive. It might be argued, then, that the practice of itinerant surgery tends to keep patients in the community and at the local hospital.

It should be stated categorically that the ethical, moral, and quality-of-care principles that the American College of Surgeons has espoused were never intended to differentiate, or discriminate, between small rural and larger suburban or urban hospitals. However, it should be noted that a recent report from the Arthur Andersen Company estimates that one in 10 hospitals nationwide will probably close by 1995. Thus, small rural hospitals seem to be more at risk for survival as their occupancy rates continue to decline.

It is of interest that during the past decade, rural areas have increasingly been serviced by a growing number of modern specialists who practice without the need to resort to itinerant surgery. The standard of practice that is exercised by these specialists has been equal to that adhered to by specialists in larger, more urban areas and demonstrates that pre- and postoperative care can be administered by the surgeon in both rural and urban settings.

Thus, maintaining a high standard of care does not necessarily limit rural area residents' access to hospitals. However, it seems that the practice of itinerant surgery has been accepted as a "matter of fact" by the officials of the AHA and that they are going to develop methods to maintain the quality of such care. One would assume that an organization that is as close to surgical education as is the AHA would recognize the fact that continuous care provided by the operating surgeon is superior to that provided by individuals who have lesser experience and training. So, it is important to realize that as more surgeons provide the total spectrum of care in rural America, "convenience" and "quality" need not be mutually exclusive.

Paul A. Ebert, MD, FACS
Director

September 1987 ACS Bulletin

Director of FACS

WATCH OUT — Creigh Gatlin grimaces and holds a support while Linda Durant drives a pin in one of several rides on the Pitt County fairgrounds Sunday. They were part of a crew erecting a swinging pirate boat in preparation for the fair's opening today. (Reflector Photo by Cliff Hollis)

The command identified the missing man as Marine Maj. Daniel S. Haworth, 34, of New Castle, Del. It was not immediately clear whether Haworth was the pilot or co-pilot of the aircraft.

and it fell into the ocean.

The Pentagon said the chopper had been "conducting routine night operations" when it crashed about 900 yards from the LaSalle, which was steaming about 30 miles

Oct 5 — Front page —

Local Doctor Receives Reprimand

By CAROL TYER
Reflector Staff Writer

The Board of Medical Examiners For North Carolina has officially reprimanded Dr. Steven M. White, a Greenville ophthalmologist, following four months of hearings.

A consent order filed by the medical examiners Thursday states the board and White have agreed that he failed in several cases to provide adequate preoperative and post-operative care to a number of his patients. It also states he delegated these duties inappropriately to non-physicians and has failed to sufficently document care.

According to the consent order, "The Board of Medical Examiners strongly reprimands Steven M. White, M.D. ..." and "... will continue to monitor White's practice to see that he complies with the requirements of this order."

The findings state that White "failed to perform an adequate preoperative examination or physical in that he delegated to optometrists, nurses or anesthesiologists the responsibility of performing these functions prior to cataract surgery."

The board states and White is reported to have agreed that "it is not consistent with the standards of acceptable and prevailing medical practices in North Carolina for the surgeon to see a patient for the first time at the time of surgery without having performed a preoperative physical or obtained a preoperative history."

The consent order filed before the Board of Medical Examiners stated that "White agrees that he will thoroughly examine each patient on whom he performs surgery prior to surgery and will review the patient's history with that patient. White further agrees that he will make an independent diagnosis of cataracts in each patient on whom he performs cataract surgery and will not rely on others to make that diagnosis. White further agrees that he will have a detailed discussion with each patient regarding the diagnosis and the nature of the surgery, advising the patient fully of the risks involved."

The findings further stated that "White did not perform the 24-hour postoperative exam following cataract surgery on certain patients ... Instead, he delegated such examination to non-physicians, including nurses and optometrists."

The board states that it and White have agreed that "delegation of the 24-hour postoperative exam following cataract surgery to non-physicians is "not consistent with the standards of acceptable and prevailing medical practices in North Carolina. It is stated that White agrees that he will perform each 24-hour postoperative exam on every patient on whom he performs surgery, with clear documentation ... except in the case of emergency, in which event, he will ensure that another ophthalmologist performs such exam."

White was also reprimanded for failing to examine certain cataract patients at all after their surgeries, failing to have appropriately detailed surgical notes for each of several patients, permitting non-physicians to sever sutures on some patients, permitting non-physicians to sign prescriptions for medicine with consultation with an ophthalmologist.

It was stated in the consent order that White has agreed to obey all laws and "agrees that he will open his records to agents of the board at any reasonable time for inspection to assess compliance with the requirements of this order.

"Failure of White to comply with this order constitutes grounds for review, after notice and a hearing, that could include revocation or suspension of his license to practice medicine."

Hearings concerning the allegations against Dr. White were conducted in March, June, July and September of this year.

Neither White nor Dr. Charles Duckett, a Greenville physician who is president of the Board of Medical Examiners and a signer of the consent order, could be reached this morning for comment.

The Weather

Forecast

Fair tonight with increasing cloudiness Tuesday. Low tonight [illegible] high Tuesday mid 70s.

New Relationship

By DON REUTER
Reflector Staff Writer

A component included in the state's new highway law has changed the partnership between the N.C. Department of Transportation and municipalities on right-of-way acquisition.

"These end[illegible] will alter the which changes the traditional balance between state and city road projects.

"No longer are municipalities required to participate in right-of-way cost for state system projects inside their corporate limits," Harrington said.

"Presently under House Bill 1[illegible]

EARLY SNOW — Howard Fish
ches of snow that fell overnight in
season downed trees in some a
Laserphoto)

Northeas
Under E

By HOWARD GOLDBERG
Associated Press Writer

Temperatures dipped into the

APPENDIX 5

Illustrations of Referral Arrangements

- O Letters and Networking Agreements
- O Case Accounts
- O Articles

May 27, 1987

Dear Dr. :

Thank you for your excellent care of Mrs. and your letter of May 13. I concur with your committment for followup care by the operating surgeon postoperatively. I believe we differ only in the amount and exclusivity of that postoperative care.

As it has been your custom to bill Medicare patients the "global fee" to cover both surgery and all followup care for 3 months, I would like to suggest a modification in your billing procedure. I have learned from Medicare that your global fee excludes payment to any other doctors for postoperative care for 90 days. This exclusion affects not only other staff doctors in your department, but also the referring doctor. In other words, neither I, nor anyone else may bill Medicare for Mrs. care for 90 days after surgery. Obviously, Medicare has always covered refractive care and optical materials, but the real issue is the patient's isolation for 3 months from her referring doctor.

I would propose that separate billing for surgery and each postoperative visit - whether performed by the operating doctor or the referring doctor - would allow more cooperative and consistent care for the patient. This will allow the patient to see both her eye doctors and, I believe, give better and more harmonious care for the patient.

Quite frankly, I cannot support a system whereby my referral to a "global fee" surgeon excludes my direct care for my patient for 3 months. An alternative is the "rebating" of postop care fees by the surgeon, but this is not a method I personally endorse.

Please consider my suggestion and discuss this issue at your discretion. I look forward to continued dialogue , as I believe this system would encourage referring doctors, especially Optometrists, to more frequently send appropriate cataract patients to . It seems that the patient's best interests are not served if excellent surgeons, such as yourself, are excluded from many Optometric patients because of a restrictive billing practice.

With my best personal regards,

Thank you for the fine care which you provided to .
: reported to our office today for post-operative refraction. At presentation he reported good, stable vision in the left eye. He went on to report that for the past week the left eye had been "watering", although no foreign body sensation was present.

Entering acuity of the left eye was 20/30+. Correction of his minimal refractive error improved acuity to 20/25, which corresponds nicely to our interferometry of November 3, 1987. Slit lamp evaluation showed the cornea to be clear and the wound healing nicely. All sutures were intact and there was no staining of the sutures. The anterior chamber was quiet and the pupil was round and reactive. No iris transillumination defect was noted. The IOL was well positioned and the capsule was intact with trace clouding. Intraocular pressure was 14mm Hg.

I am very pleased with the fine surgical result of Mr. . case. However, I am very displeased with the fact that I was not afforded the opportunity to participate in the 90 day post-operative period. I am having a very difficult time convincing myself that it was only coincidence that Mr. final visit with you was on day 92 post-operatively.

A referral relationship is based on mutual trust. My trust in you as a surgeon and your trust in my ability to provide competent care to my patients. If the trust does not exist then the relationship will not flourish. In the future I fully expect to participate in the care of my patients.

Sincerely,

O.D.

July 18, 1987

JUL 21 1987

[redacted]

Dear Dr. [redacted]

Thank you for your letter of 7-6-87 regarding [redacted] I have enclosed a copy with this letter. I have some questions about this post-operative period you mentioned in the letter (I realize dictates the letter but the post-operative question remains).

As I am sure you know the, changes in Medicare of 4-1-87 allow for the performance of post-operative services by the referring optometrist. I am comfortable doing post-operative care and feel it is in the best interest of my patients and my practice to do the follow-up care at my office.

I'm sure the fine details will be easy to resolve. I am anxious to hear from your.

Sincerely,

November 12, 1987

Dear Dr. (O.D.)

These are changing times in the eye health care delivery system. With the expansion of optometric services reimbursable by Medicare, traditional optometry/ophthalmology relationships are also beginning to change. It seems that many ophthalmic surgeons are now more aggressively seeking optometric surgical referrals.

Eye Associates is in a unique position. We can not only offer you maximum cooperation and clinical support, but also provide your patients with the most current small incision surgical techniques performed by a prominent, caring, highly qualified and experienced ophthalmic surgeon. Dr. is firmly committed to a happy and satisfied surgical patient, in addition to maintaining good, timely communication with the referring doctor. Complimentary hospital transportation services can be arranged if needed.

Please review the enclosed information. If you would like further, hands-on training in the area of post-cataract surgery follow-up care, Dr. would be very happy to work with you. Several area O.D.s have already taken advantage of this free instruction. Please call at the office to arrange a convenient time for you and Dr. to examine a number of patients together in our office

After practicing with a full time optometric associate for over 3 years, and through his affiliation with as a preceptor in the Externship Program, Dr. is well aware of the high educational level and advanced clinical capabilities of today's optometrists. As a fellow O.D. I will strive to make certain that your patients are returned to your office as soon as you feel comfortable to continue with their on-going professional eye care.

We look forward to serving you and your patients!

Sincerely

O.D.

, M.D. P.C.

, O.D.

March 1, 1988

You are cordially invited to join us for a seminar on co-management of ocular disease and maximizing reimbursement for eye care providers on Thursday March 31, 1988 at 7:00 PM at the Eye Center,

More than ever we believe through a cooperative effort our patients can obtain the best possible eye care and we can all mutually benefit.

Joining us will be , O.D., former Associate Professor of Optometry at of Optometry and , experts on Optometric coding and reimbursement.

We look forward to meeting with you.

Sincerely,

M.D.

, M.D.

JOB/GJP/jrd

Refreshments

RSVP by March 25, 1988

Pre and Post Cataract Patient Management

Does this sound familiar? A Doctor of Optometry makes a diagnosis of early cataract. The patient is counseled and told that she is not ready for surgery and is rescheduled for a follow-up in four to six months. The patient goes home, becomes somewhat anxious about her new diagnosis and then self-refers herself to a cataract surgeon. The patient (and very possibly the whole family) is lost to the doctor of optometry !

Eye Surgery Center (. is pleased to offer doctors of optometry a unique opportunity to provide quality patient care and to be involved in total patient management throughout the course of cataract development, surgical treatment and post-operative care.

This opportunity begins at the time of early cataract diagnosis. Instruct the patient that she is not ready for surgery, but if she would like a second opinion, you're familiar with several excellent surgeons. If the patient desires this second opinion, then request a consultation at . where a pre-cataract exam will confirm the diagnosis. The patient will be sent back to you for further management. Because the patient has now met the surgeon and feels comfortable, she remains in your care until you and the patient determine surgery is indicated.

At that time, the patient returns to where state-of-the-art surgical techniques are employed in a modern, non-hospital facility. Special attention is given to make the patient feel assured and relaxed throughout the procedure. Doctors of Optometry have the skill and instrumentation to provide the post-operative care in their own offices. Therefore, following surgery, your patient may return to your office.

The purpose of this course is to educate Doctors of Optometry about Current Approaches to Cataract Care and to launch this opportunity for cooperative, quality patient care delivery.

June 6, 1985

O.D.

CA

Dear

The has moved its practice to the Eye Institute, . Within the same complex we have opened The Center, which is an ambulatory surgery center dedicated to eye surgery. We are very excited about our new direction and wish to share this excitement with you.

As highly trained surgeons we wish to redirect our resources to the performance of surgical procedures and would like to enlist your cooperation in providing optometric services for our patients. We would like to have you participate in our patients postoperative optometric care and we will reimburse you for performing this service. We will also make every effort to refer nonsurgical patients to you for refractions.

We will be setting up educational seminars to inform you of the latest developments in ophthalmic surgery and will invite you to observe surgery in our facility. We will also be providing seminars to assist you in postoperative care.

If you are interested in assisting us in our redirection efforts, please contact

Sincerely,

F.A.C.M.G.A.
Medical Group Administrator

December 18, 1984

is pleased to introduce an innovative program which will significantly benefit you and your cataract patients.

As you may know, we at strive to provide the finest surgical eye care in a state-of-the-art facility. And, because our ambulatory surgery center is licensed by the state and Medicare-certified, we are able to provide our medical services at minimal cost to the patient.

Our new program affirms our dedication to providing the highest quality eye care to the elderly citizens of the . It is designed to ensure that your patients receive the optimal care available to them, and enables us to follow your patient through their entire treatment program.

We are offering to work closely with optometrists, such as yourself, to diagnose and treat cataract surgery patients. We guarantee our best effort to return your patient to your practice following surgery, and we will compensate you $100.00 per case to cover the cost of the post-operative care you will be providing. To selected optometrists that meet certain referral criteria, we are also providing, free of charge, a video cassette recorder and a custom video-tape program designed by us to educate your patients about cataract surgery, and help them feel more at ease with the procedure. Other features of our program include:

- free continuing education seminars on post-operative cataract surgery care
- free transportation for the patient and escort, if needed
- free overnight accommodation for the patient and escort on the day of surgery

We look forward to meeting with you at your office to discuss the details of our new program. We will contact you within the week to schedule an appointment.

Sincerely

April 26, 1988

[redacted]

Dear

The purpose of this questionnaire is to elicit your opinions as they relate to your opthalmology referral patterns and your interest in investing in an eye center that would provide opthalmology services. Our client is interested in developing an eye center that would serve residents and offer transportation services to the center. The center would be designed to treat those patients in need of opthalmology related surgery and would then utilize the referring optometrist for follow-up care and routine eye care. The goals of the center would be to:

-- Provide the needed care to the patients of the referring optometrist while allowing the optometrist to keep control of the patients without risk of losing the patient to the opthalmologist;

-- Allow the optometrist to have an equity interest in the center;

-- Provide the referring optometrist the opportunity to provide the necessary follow-up care required after the surgery.

Your response to this questionnaire will be handled confidentially by We would appreciate your cooperation in completing this questionnaire by May 10, 1988 and have enclosed a return envelope.

Please call me at if you have any questions. Thank you in advance for your cooperation.

Very truly yours,

Enclosures

January 13,1987

Dear Dr.

is a corporation established to coordinate referral activities between Ophthalmologists and Optometrists. also markets and administers third party eye care plans with the "Total eye care concept"

is planning to develop a program in the area.

We are seeking an Ophthalmologist to administer all tertiary eye care (medical treatment and surgery). Such an Ophthalmologist should have an established Optometric referral network or be interested in developing such a network.

Several large third party eye care plans have already been secured in your area and we would like to begin administering this plan soon.

If you are interested please fill in the enclosed form and Optinet will be contact you with further information.

Sincerely yours,

, M.D.

June 12, 1987

It was good news that the Omnibus Budget Reconciliation Act expanded Optometric services. One of the areas is postoperative care after cataract surgery. We feel that this change will strengthen the relationship between Optometry and Ophthalmology and improve the quality of care to our patients.

To help you better manage the postop patient we are having a seminar on July 13th , from 6:00 to 8:00 pm in the [redacted] Room at the [redacted] Hotel in [redacted]. Topics to be discussed will be Techniques of Cataract Surgery, Pre and Post-op management, and Common Postoperative problems. In addition we will have Mr. [redacted] Esq. discuss current Medicare laws regarding this new service.

We have applied for two continuing education credits for this meeting. Please send in the enclosed card if you plan to attend.

We are looking forward to working with you in post-op management of the cataract patient and hope to see you on July 13th.

Sincerely yours.

July 13, 1987

Dear Doctor,

We are pleased to welcome you to our seminar on Postoperative Management of Cataract Surgery.

These are certainly exciting times for Optometry and Ophthalmolgy, by working together in postoperative management, we will improve the level of care for all our patients.

As many of you are aware, we recently established the [redacted]. The [redacted] is a regional network of Optometrists and Ophthalmologists committed to perserving professional and financial integrity in todays rapidly changing eye care environment. Affiliated optometrists will be responsible for all primary eye care, while affiliated ophthalmologists will be responsible for eye care at the tertiary level.

We are extending to you an invitation to join the [redacted] as an associate member. The membership fee is $500 and includes the following:

1) $100 will be donated in your name to [redacted] Optometric Political Action Committee.

2) Quarterly seminars will be sponsored by the [redacted] the registration fee ($50- $100) will be paid in full for all associate members.

3) Optional billing will be provided for postoperative care

4) Reimbursements will be paid for postoperative care for Medicare and non-Medicare Patients.

5) We have an attorney on retainer for legal assistance on Medicare issues and collection problems.

We sincerely hope you give careful consideration to joining the [redacted].

If you are interested, please fill out the enclosed application.

Sincerely yours,

Surgeon Directors

Attending Ophthalmologis.

August 26, 1987

, O.D.

Dear Doctor

We are writing you at this time to invite you to our second Post Operative Cataract Care Seminar which will be held on September 22, 1987 at 6:30 PM. We were sorry you could not attend our first seminar of July 21, 1987, however, here is another opportunity to explore the concept of networking with you for the post-operative care of your patients. Basically, this arrangement would allow you to bill Medicare for providing post-operative care to your patients which we understand amounts to 25% of the surgical fee. It also allows you to continue being your patients' primary eye care provider.

This seminar will be held at our facility to explain the key elements of post-operative care, diagnosis and treatment of complications and normal post-operative regimen.

Enclosed is a brochure of our facility and a bulletin with a program of the evening. We ask you to respond on or before September 15th to make your reservation. Please call , Director of Public Relations, at , extension .

Thank you for your consideration and we look forward to hearing from you.

Very truly yours,

M.D. M.D.

IMPORTANT MEDICARE INFORMATION

Dear Mr. & Mrs [redacted]:

Do you know that now you can have your eye examinations covered under Medicare? Yes! Everything but the part that determines the eyeglasses prescription is covered under Medicare.

On April 1st, the "Omnibus Reconciliation Act" went into effect and enables you freedom of choice of eye doctors. Now you do not have to leave your neighborhood to have your eyes cared for. However, glasses are still not covered except after cataract surgery and, of course, you are still responsible for your $75.00 deductable and the 20% which supplemental insurances like "65 Special" pays.

If you have had cataract surgery and are wearing big, thick glasses, you may be a candidate for extended wear contact lenses or a secondary lens implant. If you are developing cataracts, we will monitor their progression until they are mature and ripe for surgery. Our surgical consultant will make all the arrangements for your operation including transportation if necessary. We will manage all your preoperative and postoperative care so that your traveling inconvenience is kept to a minimum. All the above services are provided for you under Medicare.

If you have any questions, are in any doubt concerning your benefits, or would like to make an appointment, please feel free to call our office at [redacted]. Ask for [redacted] - she's our Medicare specialist.

Sincerely,

January 27, 1988

Doctor

We have recently distributed several thousand Senior information packages to the seniors surrounding your office, however your immediate area is currently available for participation with our cataract marketing program.

We need physicians who would be able to accommodate approximately 1421 new patient cataract examinations in a 10 to 15 week period of time. Based on the response to this program in other areas, we estimate 497 of these patients will be cataract surgery candidates.

This program will be open to two to four ophthalmologists or groups in your area who qualify and would be interested in participating. The chosen participating physician(s) will have exclusive rights to the program for up to three years.

The participating physicians would agree to accept Medicare's reimbursement plus any supplemental insurance as full payment for a cataract screening, surgery, and required outpatient treatment (A-Scan, etc.). This would be only for patients.

The program is designed to operate within the guidelines of the American Academy of Ophthalmology Ethics Committee's Advisory Opinion 84-1 (Communications to the Public), 85-4 (Business Relationships Concerning Patient Referral), and 85-6 (Advertising Claims). HCFA's current determinations regarding assignment and waiver of co-payment/deductible are also accommodated.

The surgery center/hospital and anesthesiologist that participate will also be asked to waive Medicare's co-payment for their services provided to these patients. This would allow the patient to receive all required cataract treatment with no out-of-pocket medical expense.

The program will be promoted by a very effective, full color, mailing to all households in your area with a resident over 65 years of age. can usually be made compatible with your current marketing and will promote public awareness of you and your office.

We facilitate all inquiries and provide all administration for the duration of the program.

Our carefully trained patient counselors screen each caller for eligibility under the guidelines of the program and answer non-medical questions. Our staff is encouraged to take as much time as necessary to fully inform the patients and secure a quality referral. This sometimes takes more than 30 minutes per patient. If qualified, the patient is then referred to the participating physician for treatment. At the time of the call, we schedule the patient's appointment in a predetermined block of time.

We also determine if the patient is currently under the care of another ophthalmologist. As the participating physician, you will decide if you want these patients referred back to their existing doctor or referred to you.

Nearly 500,000 Age 65+ households have been contacted through the Senior [redacted] program. In several areas, more than 50% of these patients carried supplemental insurance and did not require a waiver.

With the large number of additional patients who would be referred to your office through Senior [redacted], we feel this program is beneficial to both patient and physician as well as a valued service to the community.

Dr. [redacted], if you feel you would be a good candidate for participation in the Senior [redacted] marketing program or would like more information, call me at [redacted] and I will gladly answer your questions.

Thank You

[redacted]

Consultant

P.S. The National Federation of the Blind has exclusively endorsed the Senior [redacted] program and provides a special note to all potential Senior [redacted] patients about this endorsement.

P.P.S. If you would like to talk with ophthalmologists who have participated in the Senior [redacted] program I will give you a few names when you call.

October 9, 1987

OCT 15 1987

[redacted]

Doctor [redacted],

Before reading through this letter, take a moment to look over the sample of the Senior [redacted] brochure which I've enclosed. While you may be impressed with the quality of this small part of the complete package, there are some additional facts that you should consider:

- Nearly all pieces may be fully edited to your satisfaction.
- We facilitate all inquiries including explaining Senior [redacted] to new patients, scheduling appointments, etc. YOU HAVE NO ADDITIONAL BUSY-WORK!
- The complete program includes a letter, envelope, business reply card, brochure (enclosed), endorsement note, all creative, production, postage, telemarketing, comprehensive reports to you, confirmation letters to the patient, etc.
- Senior [redacted] has been distributed to nearly 750,000 senior households from Hawaii to Florida.

A proven and effective marketing program, Senior [redacted] accomodates the needs of a practice growing and trying to keep ahead of the pack.

We are bringing this program to the [redacted] area soon. We are interviewing for one to five ophthalmologists or groups who qualify and would be interested in participating. The chosen physician(s) will have exclusive rights to the program and all referred patients for up to three years.

In [redacted] there are approximately 76,814 senior households. If this program interests you, I will send you a Profile And Projection Report which will provide actual projected returns based upon your specific needs including your office location and the number of seniors who reside near your office as well as a detailed description of our program.

If you do not own your own ASC, we would ask a [redacted] area hospital or surgery center to participate and also waive Medicare's co-payment for their services provided to these [redacted] patients. This would allow the patient to receive all required cataract treatment with no out-of-pocket medical expense.

[redacted] is designed to operate within the guidelines of the American Academy of Ophthalmology Ethics Committee's Advisory opinion 84-1 (Communications to the Public), 85-4 (Business Relationships Concerning Patient Referral), and 85-6 (Advertising Claims). HCFA's current determinations regarding assignment and waiver of co-payment/deductible are also accommodated.

[redacted] can usually be made compatible with your current marketing and will promote public awareness of you and your office. You may even include additional material in the package.

Certainly any well conceived marketing program for your office will elicit some response when mailed to all senior households in your area. But [redacted] has a proven history of patient referral throughout the US. You benefit from the expertise of Creative Marketing Design's research and development in healthcare marketing. You receive the economies of scale of working with a large national firm. [redacted] enjoys the non-paid endorsement of the National Federation of the Blind. You can even talk with other ophthalmologists who have participated and discuss real results and what patients really think.

If you would like more detailed information about [redacted] call me at [redacted]. No charge. No obligation.

(consultant)

LETTER OF AGREEMENT

To be entered into between the Eye Institute, M.D., Director and all referring Optometrists.

It is the understanding of both parties, . M.D. and ________________ that the global fee received by Dr. ______________________ is an exclusive fee for the follow up care of post-surgical cataract patients. The fee is in payment for the Optometrists provision of post-op cataract care for a period of 6 months after surgery. This fee is paid per cataract surgical patient referral. If the patient has bilateral cataracts, the fee is still $200.00 in total. There will be a slight adjustment down for patients who have Medicaid, in that the level of reimbursement of Medicaid patients is not that of other third party carriers. This downward adjustment will be on a strict ratio basis.

The global fee will be received by the Optometrist approximately 3 weeks after the cataract surgery is performed, allowing the . Institute to receive Medicare reimbursement for the surgical service.

The global fee of $200.00 per patient requiring either unilateral or bilateral cataract surgery is paid to Optometrists who have met the following requirements:

1) The post surgical patient will be seen at 3 weeks, 6 weeks, 3 months, and 6 months post cataract surgery. Additionally, the patient should be seen on more frequent intervals when other sequalae occur. Examples of such are: microhyphema, elevated intraocular pressures, cystoid macular edema, and/or secondary iritis.

2) On each evaluation the Optometrist will obtain keratometry readings, intraocular pressure readings, refraction, and best corrected visual acuity. Additionally, there will be space on the presupplied postcard for the Optometrists remarks with reference to status of the anterior and posterior segments. The card is signed by the Optometrist and mailed to the Institute so that it can be placed in the patients chart for permanent record.

3) It is understood that the patient will not be billed by the Optometrist for any follow up services during the 6 month post-surgical period. The global fee is understood to prepay and billing that would come from the Optometrists office for that period of time, and any billing from the Optometrist would be considered by Medicare to be duplication of services.

4) The Institute will be responsible for the education of each Optometrist as to dosage adjustment and titration of cortical steriods and antibiotices post-operatively to help minimize post-operative astigmatism. This education will take place in a series of 4 monthly scheduled visits by the Optometrist to Institute. During these visits the Optometrists referred patients will be seen at various stages of post-

EXHIBIT 1

October 29, 1987

Re: INC.

Dear Mr. :

Pursuant to our telephone conversation Tuesday, October 27, 1987, enclosed please find several documents which summarize the operations of , Inc., the various optometric corporations as well as the typical contract to the ophthalmologist. It is my understanding that Enterprises organizes several optometric "eye centers" which are known collectively as " ". They consist of the Eye Center, Eye Center, Eye Center, Center, Eye Center, Eye Center, Eye Center, Eye Center, and Eye Center. Mr. apparently organizes from ten to fifteen optometrists into an "eye center". Each optometrist is asked to by $3,000.00 in cash to enter as a shareholder into the corporation. The remainder of the $2,000.00 commitment comes later either as a separate cash contribution or perhaps monies coming from "dividends". Once the optometrist is committed financially, the optometrist is then encouraged to "refer any of the patients that come from the advertising or from their own practice perhaps to a closed panel of ophthalmologists". The ophthalmologist will then examine the patient in his or her own office and provide the necessary medical or surgical services for that particular patient. The particular "corporation" comprised of the optometrists and the Enterprises, Inc., will bill the third party on behalf of the ophthalmologist. The ophthalmologist then receives 42% of the collections and Enterprises, Inc., will then receive the remainder of the 58% of the fees collected. Allegedly, the 58% of the fees collected will be spent toward additional advertising, legal fees, profits as well as "dividends" which are given back to the optometrists within the "eye corporation".

I have also received a copy of the legal justification for such a scheme from the Law Offices of It is interesting that on page 7 of their report, it describes the case of U.S. v. Greber. The last sentence on the page stated that "the court stated that if one purpose of the payment made to a referring physician is to induce future referrals of Medicare patients to use the payor's services, the Medicare statute has been violated. . . ." It seems to me that this is a way for optometrists to regain part of their financial investments in the form of dividends by referring their patients with medical and surgical eye diseases to this particular closed panel of ophthalmologists. Since the eye center does the billing for these particular ophthalmologists, the profits will be returned to the optometrists in the form of "dividends". In my opinion, this is an indirect form of "kickback" or "rebate".

I certainly appreciate your willingness to take the time to peruse these various documents which also include minutes of the " Center, Inc.". These minutes were given to me by an optometrist who is presently a member of Eye Center, but indicated to me that he will probably be getting out of the program.

Any assistance that you can give us in putting these people out of business would be most appreciated by all of ophthalmology. I hope that you will be able to relate the pertinent facts from this material to the office of the Inspector General in an effort to suppress this particular scheme which, in my opinion, is a form a "kickback" and Medicare fraud. If you need specific names, addresses and phone numbers concerning the participants of both the optometrists and ophthalmologists, please do not hesitate to call or write me, and I will do my best to furnish you with same.

Sincerely,

Enclosures

Signed and mailed in the
absence of .

June 5, 1987

Dear Dr.

Thank you for taking the time to learn more about last week. We greatly appreciate having the opportunity to share our thoughts, concerns and solutions to some of the major challenges in optometric care today.

Based on your indication of interest in we have commited to formally enter the Tennessee area. We have already begun several development activities on which we intend to update you through regular communications. Once the offering memo is complete, in a few weeks, you will have the opportunity to invest. In the meantime, you will be hearing more from us -- and please feel free to contact us with any questions or ideas you may have.

I would like to underscore the commitment of the ophthalmologists, Dr. and Dr. to the creation of this eye care network. As Dr. said, the eye care market and optometrists' concerns have shifted greatly in just the last five or six years. But, the overriding mission, to provide quality eye care, remains the same -- and will be the cornerstone of policy.

Just to clarify, Drs. and will be headquartered in but will continue to serve

and other futures sites. We will be exploring a transportation system for patients to complement this network of offices.

This ophthalmologic care network will provide you and your patients high quality care, and fast communication of clinical data.

Additional benefits that will provide include:

-- Return of the patient for appropriate follow-up and the resumption of primary eye care

-- More cost efficient business office operations of your practice

-- Enhanced public awareness, image, and prestige in your community

-- Convenient source of transcript-quality, continuing education to maintain and enhance your skills

-- A source of income and financial growth through the limited partnership investment

Dr. as I mentioned, you will be hearing more from us on this very important topic. We thank you for your interest in and look forward to seeing you soon again.

Thank you.

Sincerely,

A Proposal For An
INTEGRATED EYE CARE NETWORK
For

June 1, 1987

This document is provided to you for discussion purpose only in order to solict an indication of interest, if any, and is not intended to describe the actual terms of any proposed offering of securities.

THIS DOCUMENT DOES NOT CONSTITUTE AN OFFER TO SELL ANY SECURITY AND SHOULD NOT BE CONSTRUED AS SUCH.

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is a privately held -based healthcare management firm. A majority interest is owned by practicing optometrists. The firm provides partial capitalization and complete management support in the development of integrated eye care networks. These networks relate optometry and ophthalmology for the purpose of marketing, managed care representation, continuing education, enhancing professional standards, improving the quality of patient care, and all aspects of practice management.

will provide fee-based management and marketing services to ophthalmologists. These services are particularly useful to ophthalmologists who rely heavily on communications and cooperative consultations and referrals from optometrists and physicians.

, overall strategy is primarily to promote and expand the practices of independent practicing optometrists under the marketing umbrella of

Secondarily will promote and enhance the surgical practice of ophthalmologists whose practices are being managed.

The Clinical Need

Optometrists today are facing issues not encountered just a few years ago. These may include the influence of cosmetic factors, rising costs of supplies, the need for convenient continuing education, and the loss of patients due to competition from chain organizations. The major needs which usually appear on most optometrists' list of concerns include:

1. The clinical need for an ophthalmologist who renders high quality patient care in an optometric oriented setting.

2. The need for competent, hands-on, continuing education to maintain and expand upon the clinical qualifications of the optometrists.

3. The need for an integrated approach to practice management, buying, marketing, entry into HMO's, etc.

addresses these needs. Other companies have been established to address some of these needs also. However, what distinguishes is its innovative approach, structure, and management, all of which focus upon enhancing the influence of the independent optometrists, in this rapidly changing environment.

The Business Concept

was organized by optometrists for optometrists. Obviously, no-one better understands the patient's needs than practicing optometrist. In addition, no-one better understands the needs of the optometrists in practice. While the need of the patient is for continuing high quality clinical care in a managed climate, the practitioner needs business assistance in two areas, namely:

1. Expanding revenues, and
2. Controlling expenses

A. Expanding Revenues

There are three means by which will attempt to expand patient volume, and, thereby, revenues. The first is to assist the practitioner in his existing practice. Often, referral of a patient to an ophthalmologist results in loss of the patient and family. s stated plan is for the ophthalmologist to return the patient to the optometrist for the appropriate follow-up care. This concept should result in expanded volume and revenue.

The second area of concentration is increasing the market share in each geography. The marketing strategies and advertising tactics will be designed and implemented for specific areas achieving greater recognition for each practice affiliated with a stronger collective image in the mind of the public, and, eventually, an increase in patients.

The third expansion effort will focus on winning contractual arrangements with insurance carriers, and managed care companies. The attraction of -- to these carriers is simply that the network represents an integrated eye care plan which includes the necessary elements of optometry, ophthalmology, and optical materials. Because will develop and manage such integrated networks, we are optimistic about our ability to obtain agreements with these carriers.

B. Expenses

In addition to addressing the revenue factor, will provide services designed to control and reduce the expenses of your practice. While the complete menu of services is still being defined, the following areas deserve attention:

-- Group purchasing will be offered through the Supply Company. The Supply Company will offer you ease and convenience in selection, order processing, receiving and billing.

-- Central reimbursement services will be offered to provide you with a computer-based means of dealing with claims processing.

-- Business offices services, including billing, collections, wage and salary administration and benefits planning will be offered.

-- Marketing services for your individual practice will be available. In concert with the overall, area-wide marketing services provided, these services will be specifically tailored to your individual practice and its profile.

In short, the expense reduction and control activities are designed to be broad in scope to allow the choice of services most relevant to your practice.

The Fine Print

Meeting the optometrist's needs is only one part of the concept and plan of Equally important is its innovative structure which has been specially designed for majority ownership by practicing optometrists.

establishes a wholly-owned subsidiary which will serve as the general partner of a limited partnership. The limited partners are the optometrists and the selected ophthalmologist(s). assumes complete responsibility for both developing the center and managing it on a day-to-day basis. The ownership structure is expected to be:

Optometrists -- no less than 51% !
Ophthalmologist -- no more than 24%
-- approximately 25%

By partnership agreement, the majority interest will always be held by optometrists.

Net income to the partnership will be divided exactly according to the partnership interests. If puts up 25% of the initial capitalization, it will receive 25% of the net income, not some higher disproportionate amount as some General Partners demand.

provides, and is compensated for, on-site management of the center. The fees paid to the General Partner will be negotiated prior to the writing of the limited partnership subscription documents; thus, each investor will know the fee in advance.

The General Partner secures certain services from the corporate staff of These services are charged to the partnership.

The limited partnership units can only be sold pursuant to a document called an offering memorandum. representatives will be available to discuss fully all of your concerns before you purchase a unit. The funds collected by the sale of the partnership units will be described in detail in the offering memorandum. Typically, those proceeds will be used to develop and start-up the center, including appropriate start-up operating costs.

From a financial view point, purchase of a limited partnership unit allows you to:

- -- have a stake in a business you know very well
- -- participate in a co-operative venture which is much larger than your own practice
- -- own a financial asset which may appreciate

Rather than use a pre-set formula, prefers to tailor the investment to the specific needs of each group of optometrists. The purchase price per unit, the number of units to be sold, and the use of the proceeds will be developed later.

Summary of Benefits

intends to generate significant benefits through its regional integrated eye care network. Among these are:

- -- Access to a high quality ophthalmologic referral source
- -- Fast communication of comprehensive clinical data resulting from the referral to the ophthalmologist
- -- Return of the patient for appropriate follow-up and the resumption of primary eye care
- -- Expanded practice volumes arising from the marketing activities of the network
- -- More cost efficient business office operations of your practice

-- Enhanced public awareness, image, and prestige in your community

-- Convenient source of transcript-quality, continuing education to maintain and enhance your skills

-- A source of income and financial growth through the limited partnership investment

The combination of these benefits should assist optometrists in their goal of achieving more effective patient care. The bottom line with which all agree is TOP QUALITY EYE CARE.

8-24-87 Dr. (Optom) from Lewistown, called today wanting to refer a 91 year old patient from our area for Cataract Sx. He mentioned that the patient was not real happy about having to have it done.

He then asked if we participated in the Optom-Ophthal situation whereby the Optom did the follow up care.

I mentioned to him that at this point we do not participate in that. I explained that we do no primary care x, with respect to glasses & prescriptions. I mentioned that about 80% of our patients do not have an Optom & we refer them to one post-op for their correction. Also mentioned that the PA Academy of Ophthal & Optometry have been meeting recently & until they come up c̄ a definite stand one way or the other, we will continue ~~to~~ on the ~~F/U~~ follow up care. I mentioned that this certainly is a sticky medical-legal situation & we want to try to follow along as close to the AAO rules regarding this as possible.

He then said to me that "you know he'll lose referrals if you don't participate in this type of thing". I mentioned that I knew that, but that until there was a definite ruling on this we would continue to provide the follow up care. He mentioned that he would talk to the patient and see what they wanted to do. He asked h..

Sept. 5, 1987

c/o Senator Heinz
Senate Aging Committee
G41 Durscken Blvd.
Washington, D.C., 20515

Dear Ms.

I will be calling you this week concerning the new Medicare code-modifier 54. I am an Ophthalmologist practicing and was referred to you by my local Medicare representative. I have up to now been a full Medicare participant, but am troubled by the recent changes.

Around May of this year the local medicare administrator, , based in , sent out a memo stating that Medicare would begin reimbursing optometry for postoperative care. Recently in the publication Medicare Review (included with this letter) Medicare through the local administrator stated that although traditionally posoperative care has been in the realm of the surgeon, Medicare realizes that this might be shared oy Optometry and they proceeded to say that they would split the fee in an 80 - 20 arrangement. At this point I had'nt realized the full impact of the problem because although I felt this was not in the patients best interest, I was sure that this would not effect my rural practice, however, within a week or two of this memo, I recieved a phone call from an Optometrist in , where there are several of other Ophthalmologists. The doctor asked me if I was familiar with the new Medicare modifier, and then said that if I was willing to send the patient back to him for postoperative care, he had two patients to refer for surgery. I was surprised to hear from him in the first place as I rarely received any referrals from him in the past. What was implied was that if I did not "play ball" with him, he could take those patients elsewhere.

I found this troubling because from the patient standpoint, a malpractice standpoint, and an ethical standpoint, this was poorer care. As virtually all of the postoperative patients would have to be on corticosteroids, and I would be writing prescriptions for this medication, I would be responcible for this, I would have to see these patients anyway, and it would duplicate care, thereby increasing Medicare costs (In the state of , as in most states, optometrists are not allowed to prescribe corticosteroids. On the other hand, from the business side of practice, I would risk alienating my referral base, the local optometrists, if I did'nt "play ball" with this arrangement.

I promptly called my malpractice carrier who informed me that not only would it be unethical, but it would as I had suspected, place me in a position of increased liability. I also called the American Academy of Ophthalmology and the AMA who stated virtually the same thing. The malpractice carrier had even investigated the situation with a lawyer from the Optometric licensure board in [redacted] who agreed that it was not within the scope of licence for Optometrists to do other than diagnosis in medical eye care, and that the use of corticosteroids was also not within the scope of their licence. I include the information that I have so far received in this letter. I then called [redacted] 'Medicare [redacted], and after numerous phone calls was told that I would have to deal with Washington as they were only there to carry out Medicare objectives.

In my opinion, this arrangement boils down to legalized fee-splitting. Medicare has given significant financial incentives to Opometrists who are bold enough to send their referals to eye surgeons who will cooperate with the arrangement irregardless of quality of care. I find myself in a bind, and the only way out is duplication of care. Even with that there is bound to be some confusion in the patient's mind and perhaps in their care. With the arrangement that Medicare has made, the patient through the optometrist no longer is given the better eye surgeon or the most economical one, or the most caring one, or the most convenient one or even the Medicare paticipating doctor but rather is steered toward one or another surgeon based on financial incentives by the government. I would like for you to picture yourself in the chair of your optometrist just having been told that you need eye surgery. Picture then your doctor saying that he usually refers to "so and so" eye surgeon . Can you really protest under those circumstances?

In addition to all this one must realize that training of optometrists is very variable, and although it has improved over the last few years to include cources on medical eye care, many optometrists have little or no training in post surgical care. More importantly, they have no experience in this aspect of care and in most states their licensure does'nt allow for the use of drugs nescessary to postoperative care. Certainly many good optometrists could be trained for this job, but training of practitioners "out in the field" differs greatly from the training occurring in residency programs in which there is direct supervision and errors can be picked up before they turn into real problems.

I would appreciate any help you could be in this matter. Thank you in advance.

Sincerely.

July 22, 1987

JUL [illegible] 1987
[illegible]ervice

Attention: [redacted]

Gentlemen:

I wish to lodge a formal complaint against the medical practice of [redacted]

For the past two years or so Dr. [redacted] has been referring patients with medical eye problems to local optometrists for examination, in return for surgical referral. I do not know whether a return fee is also issued, but such a practice is fairly common in this area and it is assumed that for an ophthalmologist in western [redacted] to get referrals from the local optometrists, one must pay on the order of $175 per referral.

I have had numerous patients come to me after calling his office because of a medical eye problem, who were then referred to either Dr. [redacted] OD, or Dr. [redacted] OD. These patients were told that Dr. [redacted] did not see patients except in referral and only saw patients who needed surgery.

Whereas I recognize the necessity for working with local optometrists if one is to receive surgical referrals, I do consider it unethical to refer patients with medical eye problems to optometrists for examination.

A fair number of these patients are former surgical patients of his, and many of these have come to see me. Among these I am seeing a fairly high incidence of improperly placed lenses, corneal edema due to surgery done on patients with obvious guttata, and patients with wound dehiscences who had not been informed of the complications. In some of these cases, I have obtained copies of their patient records from Dr. [redacted] and it was apparent that Dr. [redacted] was aware of the complications, but did not inform the patients of safeguards against intraocular infection. In one case, he had actually put the patient on FML in treatment of the discomfort from the accidental filtering bleb, without informing the patient either of the risk of infection, or that FML would increase that risk. After one year the patient came to me for a second opinion about what was going on.

Third, until recently the FDA has required us to file with the local hospital committees our surgical results. He gets a copy of mine and I get a copy of his. For three consecutive years, my surgical results have improved remarkably, while his have deteriorated remarkably and consistently. In 1985, he refused to submit his data. We are not required to submit data for 1986. I have brought this to the attention of the quality control committee at the [redacted] County Hospital, and they have ignored it without explanation.

Very sincerely yours,

Enclosure: Copy of Surgical Results

May 7, 1988

Dear Sirs,

In our area L [redacted] has courted the optometric referral for a number of years. About 4 years ago the optometrist who works with us in our office received a letter offering $85.00 per surgical referral. It had apparently been sent to all optometrists in our state and they had failed to note that he worked in our office. In response to that offer another ophthalmologist sent out a letter that he would meet or beat any incentive offered by the [redacted] Eye institute.

There has been much publicity about that likely being illegal and those who are making such arrangements are much more quiet about it, and it is much more difficult to obtain any information. Certainly they no longer have our office on their mailing list.

It is no secret that people travel great distances to the [redacted] Eye Institute and are often examined and have surgery the same day before returning home to areas of [redacted], and [redacted] to have the local optometrist provide the post operative care.

About three years ago an optometrist living about 80 miles from me actively courted me to get me pay him for surgical referrals since he would provide much of the postoperative care. He indicated that what he was proposing was an arrangement that he had used regularly with the ophthalmologist who had sent around information that he would match the premium paid by the [redacted] Eye institute. I did one cataract patient referred by this man. I believe tl [redacted] he patient had insisted in being referred to me. As a courtesy to the referring optometrist I had the patient stop in to see him between my regularly scheduled visits. We had a couple of telephone conversations concerning the patient and it became apparent to me that the referring optometrist lacked some basics in understanding the healing processes and what he was observing. In no way could I be involved in a situation where I was not completely in charge of the care after surgery. I will sacrifice the income in the name of my own integrity.

I have written this letter because I am frustrated with the [redacted] which asks only about the last year and require me to put a no in each blank when these battles were fought here several years ago. There are other networking arrangements which we are aware of, but to obtain proof is very difficult since the people involved seem to sense now that they are on the edge of legality and documentation is lacking.

SURGICAL CLINIC

OFFICE PHONE

July 24, 1987

Dear

I called you earlier this week trying to get some information about a problem which is facing us here in our small rural hospital in eastern , but due to one thing and another contact was not made, and finally Ms. suggested that I write you.

The situation is this. The General Hospital is located in the town of , in County which is a rural county in the eastern part of the state with no town in the county having more than three thousand inhabitants. Basically we have a general hospital with the specialists being general surgeons, internists, a radiologist, and the balance of the staff family practictioners. In addition to the general section of the hospital there is a psychiatric floor, which is under the control of a psychiatrist, and there is a skilled nursing care unit. There are no other specialists of any variety anywhereelse in the county and no other hospitals. Recently a group of opthalmologists who operate a very large opthalmological outpatient surgical clinic in the city of approached the hospital with the idea that they would come to to supply cataract surgery at our hospital for the people of this county. Their plan is to fly down on a Friday, see patients in the morning at the office of a local optometrist, operate on the patients for cataract that afternoon as outpatients using our hospital operating room suite, keep them for a short time in a recovery room, and then discharge them. The following day the patients operated upon will be seen postoperatively by an opthalmologist in the morning using the facilities of the optometrist's office. The opthalmologist will then return to , which is about 150 miles away, and presumable will not see the patient again, thus leaving the balance of the postoperative care to the optometrist, although conceiveably they could see the patient the next week when they came down to repeat the whole cycle.

Recently our hospital board approved this arrangement with the opthalmological group, and they have already leased quarters from the optometrist whose office is across the street from the hospital. About this time, members of the medical staff began to hear from several opthalmologists out in the state who stated basically that the plan of the group is not ethical, and furthermore that it depends too heavily upon optometrists for post operative care. There has been quite alot of correspondence, and we have been in a quandry as to what to do. The hospital administrator seems to think that this is all a "tempest in a teapot" as he of course is looking at the financial benefits for the hospital. The medical staff, having no resident opthalmologist around, has no idea what their standards are, and so we are torn between having a good thing financially come to the area with more conveniance for local patients, and the possibility that the whole arrangement will not be acceptabbe ethically or from the standpoint of patient care.

Recently the group from came down and presented their case to the medical staff. They had made no effort to contact the medical staff at all until their plans were questioned, but had dealt strictly with the hospital administrator. They laid great stress upon the fact that the patients would not have to go so far to get their cataracts removed, and presented the entire thing as sort of a charitable program for this rather poor rural county. They tended to pass off the fact than optometrist might be doing most of the postoperative care after the first visit, but when pushed fimally said that if the patients wanted to return to the optometrist for the balance of their postoperative care, they, the opthalmologists, could hardly do anything about it. They said the fact that they had leased space from the optometrist was purely coincidental. And finally one of them told me privately that cooperation between opthalmologist and optometrist was the wave of the future since they could get more referrals from optometrist than from family practicitioners for cataract operations and therefore opthalmology and optometry should join forces, and that the people who oppose this are just backward looking conservatives.

All of this leaves us, the medical staff a little bit uncertain as to how we should proceed. The opthalmologists have said that should any complication arise after the patient was seen postoperatively on Saturday morning, that they would fly the patient up to or would fly down themselves to take care of it. They admitted that within a range of 40 miles in several surrounding towns that do have opthalmologists, they have not been able to arrange someone who would cover for them. Any advice that you might have on this entire matter will be greatly appreciated.

Sincerely yours,

To Whom It May Concern;

There ~~is~~ an advertising campaign that has been launched on [redacted] televisions stations which I feel are of questionable ethics, validity, and a cause for concern. I believe the following information to be factual.

[redacted], an advertising promotional agency, located at: [redacted]. is a marketing group responsible for producing these commercials. They began airing on February 24, 1987 on Channel [redacted], Channel [redacted] (during the Regis Philbin Show, 9-10AM), Channel [redacted], and Channel [redacted] (2-25-87, approx.1:30PM,3-2-87 9:30 channel [redacted]).

The commercial states that they are the "[redacted]", a name illegal in New York State, unless Licensed by the State Board of Regents. [redacted] ("[redacted]") is a business entity posing as a medical entity.

This group offers cataract surgery at no cost to the Medicare patient. They also advertise free transportation, something which is not permitted in [redacted].

There is a central telephone number ([redacted] Upon calling that number, I was told by [redacted] that there would be no charge for the deductible (which is required by law) and no 20% charge. All the patient would have to do is claim that they were a hardship case with no proof of this fact required. Is the routine signing of a piece of paper to claim inability to pay a way of getting around government regulations?

A few years ago, the American Academy of Ophthalmology, in full cooperation with the government, instituted the National Eye Care Project. ~~Patients~~ who are screened for need by the project are referred to an ophthalmologist. Only those patients are released from their $75.00 deductible or 20% obligation. The doctor's other patients are fully responsible for these payments. [redacted] of the Academy can explain the policy.

The central phone clearing house gives the doctor's names, not their phone numbers. All appointments are made through the 800 number. If an appointment is to be cancelled, it must be cancelled through the same 800 number. This gives the agency control of patient volume and flow. It is possible that they assist in billing as well.

They claim that all of their doctors have been in practice for at least ten years. I know that this statement is untrue.

I placed another call and was told by [redacted] that there was a central ambulatory surgery unit where surgery would be performed at no cost. He would not give me the location. He also said that the doctors are doing this because they want to do nice things for their patients.

If the surgery is performed at an accredited hospital ambulatory facility, reimbursement is paid at the rate of 100% by the government.

It is my understanding that [redacted] has underwritten this campaign for nine doctors in th[redacted] area. They also arrange free transportation. In return for this investment, the doctors will pay [redacted] (or Cataract Institute) 50% of their surgical fee.

In a time when the government is striving to cut excesses in medical expenditures, it seems indecent to think that government (i.e., taxpayers) dollars are going not only to a physician performing surgery, but also to the advertising agency that is promoting him. Would these doctors perform the same "free", or half-price, surgery if they were not guaranteed a tremendous increase in patient volume? And would their interest in performing these surgeries lead to premature cataract extraction. Would these doctors also give their patients, or the government, the same half-price "free" courtesy?

The unwary senior citizen who is concerned about finances may be influenced by the "free" aspect, and by the false credibility of a non-medical entity using a medical name (i.e., [redacted]). Is an advertising agency, under any name, the proper source for referring patients to a qualified experienced physician, especially if they are splitting fees? How can a patient make a decision when given one or two names? Wouldn't the state or local medical society serve this need more ethically?

I do not believe that private business qualifies as medical providers and should not be the recipient of government funds, under any guise.

Television stations should be more selective or responsible before permitting this type of advertising. Quality of care and experience are the factors that should be stressed. Free doesn't necessarily mean "best". It is misleading to say "Free or No Cost" if someone, the government or insurance, is paying the bill.

How does this impact upon the rest of the medical community who abides by the HCFA regulations? There should not be a double standard of medical billing within an individual office or among the medical community. As long as the government is footing the bills, free is not free.

I am distressed by what appears to be indiscriminate, misleading advertising. If one group can advertise free, then all should be able to do so, thus the patient can concern himself with quality and not with price.

I have no objection to doctors advertising their own services if their claims are ethical, educational, and truthful

I would appreciate a response to my letter, so that I may have some piece of mind that a responsible agency will address this frightening issue.

Yours truly,

he doesn't hesitate when instinct tells him to call a physician. As a result, the M.D.'s with whom he works have begun requesting his opinions about treatment-related matters.

Innovative Patient Management

Also required for fruitful, profitable referral network participation is the use of patient management techniques that are strongly rooted in psychology, experts say. While most O.D.'s interviewed claim to have little trouble convincing patients to return to them after having seen an ophthalmologist, they attribute their lack of headaches to applying what Dr. Gallia calls "mind strategy."

Specifically, as soon as she determines that one of her patients should be seen by an ophthalmologist, Dr. Gallia tells the person that he or she is being sent to a "consultant" who works in her vision care group. She then explains the difference between optometry and ophthalmology, describes the services the M.D. will provide, and estimates when the patient can expect to return to her care.

"The operative word here is 'consultant,'" she says. "By using it, I'm able to subtly emphasize that the physician does not do primary care, and that the individual in question must come back to me for it. On the other hand, were I to say, 'I want you to visit this doctor, and then see me again,' people would be more inclined to stick with the physician."

In a related vein, Joseph Crosby, O.D., Nashville, begins the referral process by contrasting the M.D.'s role with his own. He next says, "Dr. [ophthalmologist's name] is a fine surgeon, and will do a fine job on your eyes. But our office concentrates more closely on what happens after surgery, so you should really return to us when he/she decides you can. Of course, these are your eyes, and we will honor your wishes; however, this is what's best for you.

"So far, not one person has resisted being bounced back by the physician," Dr. Crosby says. "If necessary, I repeat the explanation and the 'it's your eyes' speech more than once. Somehow, when presented in the contrasting light, the information clicks in patients' brains and they exhibit no reluctance to be funneled through the system."

A trained support staff is vital to making co-management work.

Dr. York's approach is somewhat similar, but he goes one step further by outlining what might occur should a patient inform his or her ophthalmologist of a desire to remain under medical supervision.

"Very gently, I say something such as, 'The physician has agreed not to perform services other than surgery, so it's better not to embarrass him or her by asking for a special favor,'" he notes. "Generally, it's a very effective tactic."

Training Support Staff

Finally, no matter how adept O.D.'s may become at making the co-management concept work, they must have trained staff to back them up, experts contend.

Most importantly, Dr. Reichle says, employees must attend classes sponsored by most co-management corporations. Programs should cover a broad selection of topics, including medically related eyecare procedures and what they entail, filling out insurance forms, reporting complications to the optometrist, and grappling with patients who cannot understand the referral system.

"In the co-management spectrum, staff can make you or break you," Dr. Reichle says. "They are the ones who make physicians' appointments for your patients, provide instructions for getting to the doctor's office, and answer many, many inquiries daily. Unless they can answer questions accurately, reassure people that they will receive top-quality care by returning to the O.D. following surgery, and process their insurance claims correctly, you stand to lose referrals. Thus, I wouldn't think twice about giving them time off for workshops set up especially for them."

Also valuable, Dr. Sullins finds, is holding meetings with staff members to review selected patients' cases and why they were handled in a certain manner.

"Employees need to know why you handle given referrals a certain way—why you sent one person to Dr. A and another to Dr. B, why one type of care wasn't deemed suitable for Patient C when it was fine for Patient D. The more specific you can be, the more smoothly your front office will run. And the fewer the waves there are, the more referrals you'll be able to handle."

Furthermore, Dr. Gallia has discovered that teaching her staff to track patients keeps individuals who have been referred to ophthalmologists from "falling through the cracks." Several times each month, the staff reviews her records to determine whether any of her postoperative patients have failed to make an appointment for an optometric examination. Those who haven't contacted her office on schedule receive repeated telephone reminders to schedule a consultation with the O.D.

"Everyone follows strict instructions to call reticent patients to find out why they are not coming in," Dr. Gallia says. "If they discern any hesitancy, they come straight to me. They're the liaison between my door and the ophthalmologists', and it's just as much their job to funnel patients as it is mine." CM

2/88
Review of Optometry

CARING FOR THE ELDERLY

HOW TO CO-MANAGE CATARACT PATIENTS

Dean Domic, O.D.
Oklahoma City, Ok.

To do a good job of managing our cataract patients, we need a thorough understanding of how to prepare our patients for surgery, and how to diagnose and handle any complications afterwards.

This article explains how to set up a co-management program, how to work with the surgeon and what to look for after the surgery is complete.

When you have decided that your patient needs cataract surgery, the first step is to discuss your recommendations with him.

After you have explained the benefits of the surgery, and believe there is a desire to procede, tell the patient what to expect.

Explain that the surgery will take only two to three hours and is usually performed on an outpatient basis.

Most patients will also want to know the type of anesthesia used during the surgery and whether they will be awake for the procedure. Ask your surgeon if he uses a narcoleptic anesthetic to put the patient into a light sleep and/or retrobulbar injections to control pain and eye movements.

Explain to the patient that his activity will be restricted after surgery. Strenuous activity and rubbing the operated eye are prohibited because they can pop the wound open. Patients should not lift anything over 30-40 pounds during the first six weeks after surgery. Bending and stooping are sometimes allowed.

During the first six to eight weeks after surgery, the patient should wear a shield over the operated eye while sleeping.

Some patients may have to take a leave of absence from work or switch to a desk job. Sometimes, it's more convenient to plan the surgery for a particular season of the year.

After you have prepared the patient, and determined a timetable for the surgery, see if you can schedule the surgery before the surgeon even meets the patient. We find that surgery goes most smoothly when the surgeon can perform the A-scan ultrasound readings, potential acuity tests, and other tests on the day of or the day before surgery. This way, the patient doesn't have to make multiple trips to the surgeon's office.

After you have scheduled surgery, prescribe topical broad spectrum antibiotic eye drops such as gentamycin, tobramycin, or chloramphenical, for a few days before surgery to prevent infection. Try to follow the surgeon's usual schedule for starting and stopping these drops.

Finally, prepare a report for the surgeon that includes current spectacle Rx, latest refraction and best corrected visual acuity. The surgeon needs this information to calculate the patient's IOL power. Also on this report, advise the surgeon if the patient has had any previous reactions to medications.

A couple of notes about providing pre-operative care:

- If you haven't done so already, it's worth your while to visit the surgeon's office to get a working knowledge of the surgeon's usual pre-operative, operative and post-operative routines.
- Make sure you and the surgeon both provide the patient with the same information and instructions.

The post-operative exam

After the patient has had surgery, you can immediately take over the patient's care.

The surgeon will usually perform the first exam himself on the day after surgery. Make sure you receive the exam results.

After that, schedule an exam at five to eight days, three to five weeks, six to eight weeks, and three and six months after the surgery.

Your follow-up exam should be generally the same for each visit: a subjective evaluation by the patient, visual acuities, refraction, biomicroscopy, tonometry and fundus exam.

You should also perform a thorough dilated retinal evaluation with binocular indirect ophthalmoscopy at the three or six month visit, or sooner if you suspect a retinal problem. One note: It's generally safe to dilate patients with anterior and posterior chamber implants. It's probably not safe to dilate patients with an iris fixated lens.

Notify the surgeon of any complications. We keep our surgeon abreast of the patient's progress by means of a post-card mailed in after each exam.

Trouble Shooting

Patients depend on you to determine if certain symptoms are "normal" or acceptable. Gear your

Pro-Optometric-News

A Newsletter for the Optometric Professional

A Service of the Eye Referral Center

Eye Referral Center Opens in

The much discussed Center, a new model ophthalmologic testing and surgical center, is now officially open. Located in , it is the first optometric referral center to actively involve optometrists in diagnosis and treatment roles.

According to Dr. , Washington Twp. optometrist and Center Director, the Center is founded upon the philosophy that the optometrist is the primary care provider and entry point for all eye care.

The Center is a state-of-the-art ophthalmologic testing and surgical facility, designed to support the Optometric Profession by providing the most modern equipment and knowledgeable clinical expertise. Because the center is an open professional association, optometrists can choose to participate in a variety of roles. Dr. points out the benefits:

"The referring optometrist retains control of the patient. Supported by Center staff, he/she may elect to conduct tests, interpret results, or plan treatment, and perform post-surgical treatment as he/she feels appropriate. Referring optometrists can become proficient in additional professional skills through hands-on equipment training and by taking advantage of the Center's CE programs."

Dr. , Board Certified Ophthalmologist and Center Medical Director, states that the Center provides a comprehensive range of services. As a testing facility, the Center performs state-of-the-art tests such as Endothelial Cell Counts, A-Mode and B-Mode Ultrasonography, and much more. As a surgical facility, the Center is equipped with Nd YAG, Argon, and Krypton Lasers. Additional procedures are performed at the Surgical Center of the Health Systems, located next door to the Center.

The Center accepts no referrals outside its member network. Dr. adds that the Center does not perform refractions, and in fact, maintains no equipment to do so.

"The Center will significantly change how optometrists refer patients," says Dr. . "For the first time, an optometric referral center exists that makes us an integral part of the treatment team."

, is an open professional association. It requires no entrance fee or other financial obligation. If you would like more information concerning how the Center can benefit you, please call us at . We will be happy to arrange a personal visit to the Center for you.

APPENDIX 6

OPHTHALMOLOGY/OPTOMETRY RELATIONSHIPS INVOLVED IN CATARACT SURGERY

OFFICE OF INSPECTOR GENERAL

OFFICE OF ANALYSIS AND INSPECTIONS

OCTOBER 1988

Office of Inspector General

The mission of the Office of Inspector General (OIG) is to promote the efficiency, effectiveness, and integrity of programs in the United States Department of Health and Human Services (HHS). It does this by developing methods to detect and prevent fraud, waste and abuse. Created by statute in 1976, the Inspector General keeps both the Secretary and the Congress fully and currently informed about programs or management problems and recommends corrective action. The OIG performs its mission by conducting audits, investigations and inspections with approximately 1,200 staff strategically located around the country.

Office of Analysis and Inspections

This report is produced by the Office of Analysis and Inspections (OAI), one of the three major offices within the OIG. The other two are the Office of Audit and the Office of Investigations. The OAI conducts inspections which are typically short-term studies designed to determine program effectiveness, efficiency, and vulnerability to fraud or abuse.

This Report

Entitled "Ophthalmology/Optometry Relationships Involved in Cataract Surgery." This inspection was conducted to determine the frequency of referrals between ophthalmologists and optometrists, and the extent and appropriateness of payments to optometrists for postoperative cataract care.

The report was prepared under the direction of Don McLaughlin, The Regional Inspector General of Region VII, Office of Analysis and Inspections. Participating in this report were the following people:

Kansas City Region	Headquarters
Tim Dold (Project Leader)	Kitty Ahern
Deborah Walden	Jeff Balentine
Philip O'Hare	Mary Hogan
James Wolf	Barry Steeley

OPHTHALMOLOGY/OPTOMETRY RELATIONSHIPS INVOLVED IN CATARACT SURGERY

RICHARD P. KUSSEROW
INSPECTOR GENERAL

OCTOBER 1988

Control #OAI-07-88-00460

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EXECUTIVE SUMMARY

OBJECTIVES: This inspection focuses on issues involving optometrists' providing postoperative care to Medicare beneficiaries following cataract surgery. The overall objectives of the inspection were to determine:

- the extent and frequency of postoperative care by optometrists;
- the extent of referral arrangements between ophthalmologists and optometrists;
- the manner of billing by ophthalmologists and optometrists for cataract surgery when an optometrist provides postoperative care; and
- whether the practice of optometrists' providing cataract surgery postoperative care could lead to abusive referral arrangements, possible duplicate billings, and quality of care problems.

BACKGROUND: This program inspection was requested by the Administrator of the Health Care Financing Administration (HCFA), who was concerned about the issue of optometrists' providing postoperative care to Medicare beneficiaries who had cataract surgery. This practice increased after Medicare coverage was expanded by the Omnibus Budget Reconciliation Act of 1986. This legislation permitted coverage of optometrists as physicians for any services they are legally authorized to perform in the State in which they practice. Forty-eight States permit optometrists to use diagnostic drugs. Further, 21 of those States have passed legislation allowing optometrists to use and prescribe therapeutic drugs, greatly expanding their scope of practice and ability to treat patients during the postoperative period following cataract surgery.

METHODOLOGY: Preinspection work included meetings and contacts with the American Academy of Ophthalmology, the American Optometric Association, State licensing boards, Medicare carriers, and HCFA staff.

A random sample of eight Medicare carriers was selected. Two carriers were randomly selected twice. One hundred claims "histories" for patients who had undergone cataract surgery were randomly selected for review from each sampled carrier (200 from those selected twice). These histories were analyzed to determine the extent to which ophthalmologists

delegate postoperative care to optometrists, and the extent to which optometrists are reimbursed for postoperative care already billed by the ophthalmologists as part of a global fee covering both surgery and postoperative care.

The eight carriers also provided a separate sample of the names of 60 ophthalmologists who perform cataract surgery for Medicare beneficiaries. One-half of these surgeons were selected from among the highest-paid ophthalmologists at each carrier and the other half from those receiving the mid-range of payments. Fifty-eight of the 60 surgeons were interviewed regarding their practice. The surgeons were requested to provide a sample of names of optometrists handling aftercare, and a sample of names of cataract surgery patients. The optometrists and patients were interviewed to obtain their opinions on the issues of optometrists' providing cataract surgery referrals to ophthalmologists and optometrists' providing postoperative care.

In addition, peer review organizations (PROs) and State Boards of Optometry were contacted in each of the sampled States to discuss their experiences and opinions regarding these issues.

FINDINGS:

MEDICARE MAY BE PAYING TOO MUCH FOR POSTOPERATIVE CARE FOLLOWING CATARACT SURGERY

- The number of postoperative days encompassed by the global fee varies by carrier, as does the percentage of the global fee allocated to surgery versus postoperative care. As a result, in some cases Medicare is making additional payments for postoperative care which would be included in the global fee by other carriers.

- In 97 percent of cataract surgery cases reviewed, the ophthalmologists billed a global fee. In a small number of these cases, optometrists also billed Medicare inappropriately for services during the period encompassed by the global fee.

THERE IS A DIRECT CORRELATION BETWEEN THE EXISTENCE OF REFERRAL ARRANGEMENTS AND THE USE OF OPTOMETRISTS FOR FOLLOW-UP CARE

- Forty-six percent of the highest-paid ophthalmologists sampled referred cataract surgery patients to optometrists for postoperative care, in contrast to 10 percent of the ophthalmologists receiving mid-range payments.

- Ophthalmologists who refer cataract surgery patients to optometrists for postoperative care receive a higher percentage of their surgical referrals from optometrists than do ophthalmologists who do all postoperative care themselves (32 percent versus 7 percent). States that allow optometrists to prescribe therapeutic drugs had a higher overall percentage of optometric referrals.

THE INSPECTION YIELDED NO DIRECT EVIDENCE OF POOR QUALITY CARE; HOWEVER, THERE ARE SOME VULNERABILITIES

- Ophthalmologists who refer their patients to optometrists for postoperative care, compared to those who perform their own postoperative care, generally follow their patients for a shorter postoperative period. However, most optometrists said that although they provide postoperative care, they only treat routine complaints, and would refer patients back to ophthalmologists for treatment of serious complications.

- Regarding second opinions, over half the ophthalmologists stated they have provided Medicare patients with second opinions for cataract surgery. However, only twenty percent of the patients said they had requested a second opinion before undergoing cataract surgery.

RECOMMENDATIONS:

TO IMPROVE MEDICARE PAYMENTS FOR CATARACT SURGERY

- The HCFA should develop national guidelines covering the number of postoperative days included in a global fee for cataract surgery, and the percentage allocation of a global fee to surgery and postoperative care.

- The HCFA should require all carriers to instruct optometrists and ophthalmologists in the use of procedure code modifiers, and to establish screens for duplicate billing within the global-fee period. HCFA should also identify ophthalmologists most likely to refer cataract surgery patients to optometrists for postoperative care. Such referrals would provide for a focused postpayment review of cataract surgery patient records to insure appropriate billings.

TO ADDRESS REFERRAL ARRANGEMENTS THAT MAY VIOLATE THE ANTI-KICKBACK PROVISIONS

- The HCFA should require carriers to refer any potentially abusive arrangements between ophthalmologists and optometrists, which the carrier identifies, to the Office of Inspector General for investigation.

TO IMPROVE QUALITY OF CARE FOR CATARACT SURGERY PATIENTS

- The HCFA should require PROs to work with their State Boards of Optometry to establish protocols for postoperative cataract surgical care. Such protocols should address the minimum number and frequency of postoperative visits, the necessity for 24-hour availability of emergency care, and the presence of written agreements between referring practitioners regarding the division of responsibilities. These protocols should become part of the PROs' review of cataract surgery in both inpatient and ambulatory settings.
- The HCFA should require mandatory second surgical opinions for elective surgeries, such as cataract surgery, paid under Medicare.

INTRODUCTION

OBJECTIVES

This inspection focuses on issues involving postoperative care rendered by optometrists to Medicare beneficiaries following cataract surgery. The overall objectives of the inspection were to determine:

- the extent and frequency of postoperative care by optometrists;
- the extent of referral arrangements between ophthalmologists and optometrists;
- the manner of billing by ophthalmologists for cataract surgery when an optometrist performs postoperative care; and
- the extent of services provided by an optometrist during the period for which an ophthalmologist bills a global fee.

BACKGROUND

This program inspection was requested by the Administrator of the Health Care Financing Administration (HCFA) who was concerned about ophthalmologists' referring cataract patients to optometrists for postoperative care after performing cataract surgery. The concern stemmed from a statement by the American Academy of Ophthalmology (AAO) regarding adherence to professional ethical standards. According to the AAO, operating surgeons are responsible for providing postoperative care to their patients. Further, surgeons who turn over their responsibility for postoperative care to someone else do not fulfill their responsibilities to the patient. In addition, the bylaws of the American College of Surgeons state that it is unethical to turn over postoperative care of a patient to another physician who is not as well qualified to undertake it. Their concern is that the quality of postoperative care provided by someone other than the surgeon may be poor and result in placing the patient at greater risk.

Nature of Surgery

Cataracts of the eye occur when the natural crystalline lens inside the eye becomes cloudy. Cataracts can occur at any age, but are more prevalent in the elderly population. Due to the aging process, the natural lens becomes hard and unable to focus. This progressive process may eventually result in blurred vision or even blindness. Surgery is the only effective way to remove a cataract. Vision can be restored after the natural lens of the eye is removed and a permanent intraocular lens (IOL) is implanted inside the eye. Cataract glasses or contact lenses are used for candidates not suitable for IOL implants, although even those with an IOL implant usually require eyeglasses for reading, sewing, or other activities.

Due to technological advances over the last 10 years, cataract surgery is highly successful; the patient's vision can be restored in up to 90 percent of all cataract cases. However, according to medical studies, increasing patient age, surgical problems, postoperative complications, and adverse reactions are among the factors which could reduce visual acuity after cataract surgery. It is estimated that medical complications following cataract surgery may occur in about 3 to 5 percent of the cases but would not necessarily result in a loss of vision if recognized and treated properly. The postoperative recovery period usually lasts 6 to 12 weeks, during which time the eye heals and visual rehabilitation takes place.

Medicare Coverage

Under Medicare, vision care services are limited to those necessary to treat eye diseases such as cataracts. Cataract surgery as well as preoperative and postoperative care are covered by Medicare when medically necessary. Cataract surgery is considered major eye surgery with a potential for complications and is one of the most frequently performed procedures in the Medicare population. The Office of Inspector General (OIG) estimates that over $1.2 billion was reimbursed by Medicare for the two most common cataract surgeries with lens implants in 1986.

Cataract surgical care for Medicare beneficiaries is covered by a global fee that includes surgery and postoperative care. The Medicare carrier establishes the global-fee period using criteria developed from medical practice in the carrier's service area. The surgeon provides all the services during the global-fee period, e.g. 90 days, when a global fee is billed. When the surgeon provides some of the services, e.g. surgery only, and the postoperative care is provided by another physician, the two-digit modifier "54" should be used on the bill to indicate surgical care only. When only postoperative care is provided, the modifier "55" should be used to show postoperative management only. Carriers are required to screen bills for eye care services within the global-fee period to avoid inappropriate or duplicate payments.

In 1980, the Omnibus Reconciliation Act authorized Medicare payments to optometrists for services related to cataract surgery (Section 937 of Public Law 96-499). Until March 31, 1987, optometrists were covered by Medicare for examination services related to aphakia (the absence of the natural lens in the eye). Optometrists could only bill Medicare for determining visual acuity, prescribing glasses, and dispensing optical devices to patients who had had cataracts removed, although the State may have allowed them to perform a wider range of services.

Effective April 1, 1987, Medicare coverage of optometrists' services was expanded with Section 9336 of Public Law 99-509 (the Omnibus Budget Reconciliation Act of 1986). This expansion allowed Medicare coverage of optometrists as physicians (as defined in the Social Security Act governing Medicare) in providing cataract surgery postoperative care, within the legal authorizations of the States in which they practice. However, this expansion of coverage raises questions about the division of responsibility between the ophthalmologists and optometrists regarding appropriate patient care and billing to the Medicare program.

Licensure Issues

There is no uniform set of optometric services covered by Medicare, since State licensure laws vary widely. Qualifications, training requirements, and the scope of practice for optometrists are established under State law. In this regard, 48 States permit optometrists to use diagnostic drugs. Twenty-one of those States also permit optometrists to prescribe therapeutic pharmaceutical agents, which significantly expands the optometric scope of practice and the ability to treat some postoperative complications. Postoperative cataract care was within the scope of practice of an optometrist in the seven States included in the inspection sample. All seven States permit optometrists to use diagnostic drugs, and three of the seven also allow the use of therapeutic drugs.

OIG Concerns

The OIG is concerned with situations in which abusive referral arrangements result in Medicare overpayments and kickbacks. Postoperative care by someone other than the surgeon raises concerns over global reimbursement to surgeons who perform only cataract surgery and not postoperative care. In addition, patient referrals between optometrists and ophthalmologists (so-called networking) could result in improper payments. The OIG has identified potential vulnerabilities, including coercion to refer patients and failure to adequately provide preoperative and postoperative care. Instances of these potential vulnerabilities have been identified in complaints to the OIG and/or to the Senate Committee on Aging.

METHODOLOGY

A random sample of eight Medicare carriers was selected. Two carriers were randomly selected twice. The selected carriers processed claims for beneficiaries in Northern and Southern California, Louisiana, Montana, Western Missouri, Upper New York State, North Carolina, and Oregon. (See appendix I.) Each carrier was requested to identify all beneficiaries who received one of four specified cataract services during the period April 1, 1987 through March 31, 1988. Each carrier then provided beneficiary payment histories for a random sample of 100 of the identified beneficiaries (200 for those selected twice). The total sample of 1,000 beneficiaries who had cataract surgery represented 1,062 procedures, since some beneficiaries received surgery on both eyes.

In addition, the eight carriers provided the OIG with the names of a sample of ophthalmologists who: (1) received the highest Medicare payments in that specialty; and (2) were paid in the mid-range of payments during fiscal year 1987. Of the 60 names of ophthalmologists provided by the carriers, 58 were contacted. We were unable to contact the remaining two.

The ophthalmologists we talked to provided us with the names of 49 patients who had received cataract surgery. Those who refer their cataract surgery patients to optometrists for postoperative care also provided us with the names of 28 of these optometrists.

The ophthalmologists, optometrists, and patients were contacted in person or by phone and interviewed using discussion guides. Opinions were obtained regarding the issue of optometrists' providing referrals and postoperative care following cataract surgery, second opinions for cataract surgery, and the effect of cataract surgery on the patient's life.

Peer review organizations (PROs) and the State Boards of Optometry were contacted in each of the sampled States. The organizations were queried on the extent of postoperative care by optometrists after cataract surgery in their States, and whether they were aware of positive or negative outcomes of this practice.

FINDINGS

MEDICARE MAY BE PAYING TOO MUCH FOR POSTOPERATIVE CARE FOLLOWING CATARACT SURGERY

a. Variance In Postoperative Days and Global Fees

There are no specific HCFA guidelines regarding:

- the number of postoperative days covered by a global fee; and
- the percentage or amount of the global fee allocated for the surgery and postoperative care.

This leads to nationwide variances in postoperative days covered by Medicare and in the amounts allocated to surgery and postoperative care. Through our contacts with the eight Medicare carriers included in this inspection, we found that the global fee covered postoperative periods ranging from 10 to 120 days.

We asked the 58 ophthalmologists their opinions about the appropriate length of the postoperative period of recovery following cataract surgery. The average number of postoperative days identified in these interviews was 84, ranging from 10 to 365 days.

Where the carrier's global-fee postoperative period is 10 days, both ophthalmologists and optometrists can begin billing for services rendered on the 11th day, one day following the end of the carrier-established global-fee postoperative period. This very short global-fee postoperative period allows additional program payments that could be avoided if national guidelines on the number of postoperative days in a global fee were developed which included a greater number of days in the postoperative period.

We also found the portion of the global fee allocated for postoperative care varied among carriers. Three of the eight carriers utilized a 70/30 global-fee split between the surgical procedure (70 percent) and postoperative care (30 percent). Other carriers based postoperative allocations on specific procedure codes, made adjustments after a review of the charges, or used no modifier or global-fee split at all.

b. Optometry Services Billed During the Global-Fee Period

Ophthalmologists billed Medicare a global fee for cataract surgery in over 97 percent of the 1,062 cataract surgery cases reviewed. The global fee covers both the surgical procedure and postoperative care. In 25 of the cases covered by a global fee, optometrists also billed Medicare. In 10 of these cases, the services provided by the optometrists were outside the global-fee period. However, in the remaining 15 cases (60 percent) the services were performed within the global-fee period. These services represent a potential overpayment of $826 because carriers did not deny these services even though a global fee was billed by the ophthalmologists. The HCFA requires that Medicare carriers establish a screening mechanism that will allow for identification of inappropriate or duplicate services.

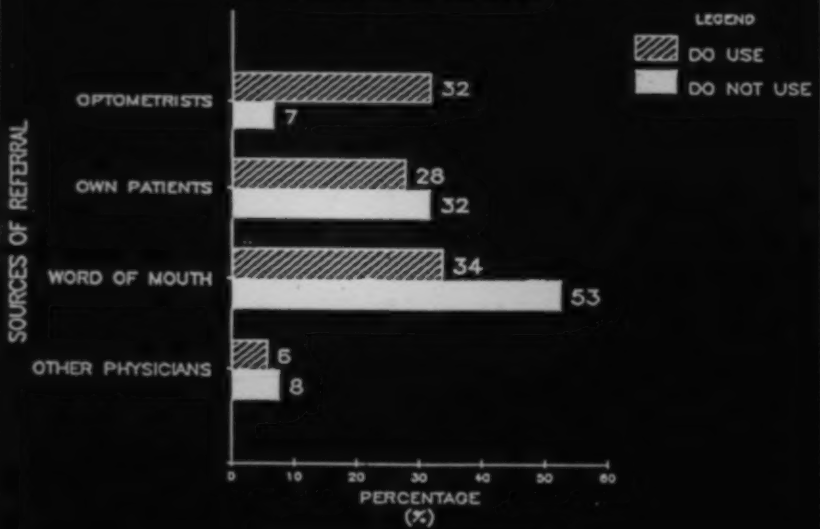
The $826 potential overpayment found in this study is small; however, in 25 cases optometrists billed for postoperative care covered by a global fee and in 15 of those cases (60 percent) optometrists billed for services performed within the postoperative period covered by a global fee. This 60 percent rate indicates a potential vulnerability which is much greater than the small overpayment found in this study.

THERE IS A DIRECT CORRELATION BETWEEN THE EXISTENCE OF REFERRAL ARRANGEMENTS AND THE USE OF OPTOMETRISTS FOR FOLLOW-UP CARE

a. Optometric Referrals For Cataract Surgery

The inspection found that 46 percent of the highest-paid ophthalmologists sampled allow optometrists to provide postoperative care to their cataract surgery patients, in contrast to 10 percent of those in the mid-range of payments. We also found that sampled ophthalmologists who allowed optometrists to provide their cataract surgery patients with postoperative care received 32 percent of their cataract surgery patients through referrals from optometrists. Ophthalmologists who did not refer their patients to optometrists for postoperative care received only 7 percent of their cataract surgery referrals from optometrists. (See figure 1.)

Figure 1
COMPARISON OF OPHTHALMOLOGISTS WHO DO USE OPTOMETRISTS WITH THOSE WHO DO NOT USE OPTOMETRISTS FOR POSTOPERATIVE CARE BY SOURCES OF REFERRAL



(ALL FIGURES ARE PERCENTAGES %)

We identified two examples of contractual agreements between ophthalmologists and optometrists. In the first situation, an optometrist is employed by an ophthalmologist's corporation as a part-time salaried employee. He receives both a monthly salary and reimbursement for services performed for corporation patients. The corporation has a number of formal agreements with area nursing homes to provide total eye care to their patients. Through this arrangement, the optometrist visits nursing home patients using a mobile examination unit supplied by the corporation. The optometrist examines patients and, by agreement, refers nursing home patients requiring ophthalmological services (e.g., cataract surgery) to the corporation ophthalmologist. The optometrist then provides these patients with postoperative care in the nursing homes. The second example consists of an ophthalmologist who leases space from an optometrist in which to examine cataract surgery and other patients. We have referred both situations to the Office of Investigations for their determination of any potential violations of the anti-kickback statutes.

The average percentage of optometric referrals to the sampled ophthalmologists varied by State, ranging from 5 to 28 percent. The highest percentages of optometric referrals occurred in those States that permit optometrists to provide therapeutic drugs. (See figure 2.)

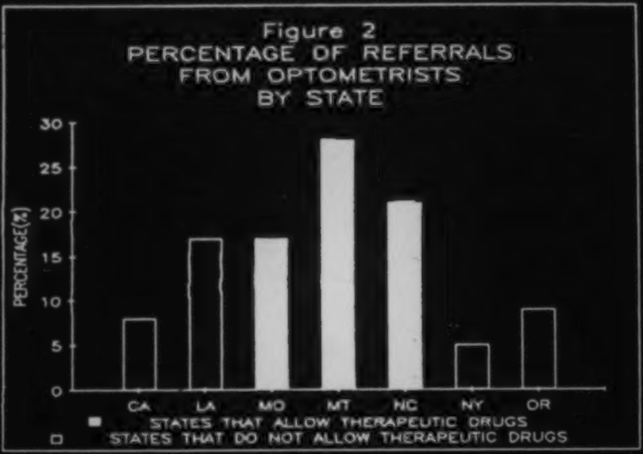


Figure 2
PERCENTAGE OF REFERRALS FROM OPTOMETRISTS BY STATE

b. Optometrists' Providing Postoperative Care

An examination of three sources of data revealed that:

- sixteen of 58 ophthalmologists interviewed (nearly 28 percent) allow optometrists to provide postoperative care to their cataract surgery patients;
- in 25 of 1062 cases reviewed optometrists inappropriately billed for postoperative care; and
- eighteen of 49 patients interviewed (nearly 37 percent) stated they saw a doctor other than the surgeon for postoperative care. In some instances the patients were not certain if the doctor was an ophthalmologist or an optometrist.

A comparison of data between the 16 ophthalmologists who allow optometrists to provide postoperative care and the 42 who do not is shown in appendix II.

Ophthalmologists reported the major reason patients returned to an optometrist for postoperative care was the distance involved in traveling back to the operating surgeon. Optometrists stated that patients preferred to return to their local physician for care; this was confirmed by almost half of the patients who received cataract surgery. They stated that travel was required to receive cataract surgery since it was not available in their communities.

All 28 optometrists interviewed stated they provide cataract surgery postoperative care, and feel confident in monitoring these patients for the detection of complications that would require the patients' return to the ophthalmologist. However, 17 (61 percent) said they only treat routine complaints and complications such as blurred vision, redness of the eye, and a slight increase in intraocular pressure. Thirteen of the 17 are in States that allow optometrists to provide therapeutic drugs to treat eye conditions, but only 1 of the 13 said he would attempt treating a serious complication, and then only after conferring with the operating ophthalmologist. The remaining 11 would provide only routine eye exams and refractions, and monitor the eye for increases in pressure and other indications of complications. These 11 optometrists indicated that patients with any indication of a complication would be referred back to the ophthalmologist for treatment.

The ophthalmologists interviewed were significantly divided on the issue of optometrists' providing cataract surgery postoperative care. We found that the majority of those ophthalmologists interviewed believed that optometrists are not qualified to provide postoperative care. The majority also stated that the services provided by an optometrist during postoperative care are not as comprehensive as the services provided by an ophthalmologist.

THE INSPECTION YIELDED NO DIRECT EVIDENCE OF POOR QUALITY CARE; HOWEVER, THERE ARE SOME VULNERABILITIES

a. Second Opinion For Cataract Surgery

The physicians interviewed stated that second opinions were requested as a requirement for private insurance. Thirty of 58 (52 percent) ophthalmologists stated they received requests for second opinions, and 11 of 28 (39 percent) of the optometrists provided Medicare patients with second opinions regarding cataract surgery. Ten of the 49 (20 percent) Medicare patients we interviewed stated they sought a second opinion before undergoing cataract surgery. Six of the 10 patients sought a second opinion from an ophthalmologist, and the remaining 4 saw an optometrist for the second opinion. This study did not attempt to determine the medical necessity of the 1,062 surgeries reviewed. However, cataracts develop slowly, and surgery may be avoided for many years if the patient so desires. Additionally, cataract surgery should not be performed unless eyesight is expected to improve.

The OIG has previously recommended that legislation be adopted to require a mandatory second opinion program for elective surgeries for Medicare patients.

b. Potential Causes of Poor Quality Care

Ophthalmologists who refer their patients to optometrists for postoperative care, compared to those who perform their own postoperative care, were found to follow their patients for a shorter postoperative period. However, most optometrists said that although they provide postoperative care, they only treat routine complaints, and would refer patients with evidence of a serious complication back to ophthalmologists for treatment.

RECOMMENDATIONS

TO IMPROVE MEDICARE PAYMENTS FOR CATARACT SURGERY

The HCFA should require all carriers to:

- develop national guidelines covering the number of postoperative days (e.g. 60 to 90 days) that should be included in global fees, and the percentage allocation of global fees to surgery and postoperative care (e.g. 80/20). These guidelines should allow sufficient postoperative time to complete all necessary postoperative exams and procedures, with the exception of complicated cases.
- instruct both optometrists and ophthalmologists in the use of modifiers when cataract surgery postoperative care is shared with or provided by an optometrist;
- identify ophthalmologists most likely to permit postoperative care by optometrists. (The inspection found the highest-paid ophthalmologists to be most likely to share cataract surgery care with optometrists.);
- have the necessary screens in place to detect services billed within a global-fee period; and
- conduct postpayment reviews of cataract surgery to determine:
  - if providers are correctly billing and using modifiers;

- if optometrists are being paid for services already paid to the ophthalmologist in the global fee; and
- the possible existence of arrangements which might violate anti-kickback statutes.

TO ADDRESS REFERRAL ARRANGEMENTS THAT MAY VIOLATE THE ANTI-KICKBACK PROVISIONS

- The HCFA should require carriers to refer any potentially abusive arrangements between ophthalmologists and optometrists, which the carrier identifies, to the Office of Inspector General for investigation.

TO IMPROVE QUALITY OF CARE FOR CATARACT SURGERY PATIENTS

- The HCFA should require mandatory second surgical opinions for elective surgeries paid under Medicare. Cataract surgeries, which are basically elective, would be included for mandatory second opinions by another ophthalmologist.
- The HCFA should require PROs to work with their State Boards of Optometry to establish review procedures for postoperative cataract surgical care. Such review procedures should address the minimum number and frequency of postoperative visits, the necessity for 24-hour availability of emergency care, and the presence of written agreements between referring practitioners regarding the division of responsibilities.

APPENDIX I

OPHTHALMOLOGY/OPTOMETRY SAMPLE

CARRIER	STATE
Arkansas Blue Shield, processing claims for	Louisiana
Blue Shield of California	California (Northern)
Transamerica Occidental of California*	California (Southern)
Blue Shield of Kansas City	Missouri (Western)
Blue Shield of Western New York, Inc.	New York (Does not include New York City)
Prudential of North Carolina*	North Carolina
Aetna of Oregon	Oregon
Blue Shield of Montana	Montana

*Two separate samples of 100 each

OPHTHALMOLOGIST COMPARISON DATA

The inspection found that of the 58 interviewed ophthalmologists who perform cataract surgery, 16 (28 percent) said they approved of optometrists' providing their patients with cataract surgery postoperative care. The remaining 42 (72 percent) felt that optometrists were not qualified to provide postoperative care. The comparison of data between both groups is outlined below. The comments address ophthalmologists who allow postoperative care by optometrists.

Data	Allow Postop Care (16)	Do Not Allow Postop Care (42)	Comments
Average number of years in practice	13	18	Averaged fewer years in practice
Percentage of practice with Medicare patients	79%	59%	Had a higher Medicare patient population
Percentage of cataract surgery performed at:			Performed a higher percentage of their surgeries in an ambulatory center (ASC)
(a) Hospital surgical out-patient	26%	71%	
(b) ASC	74%	28%	
Percentage of cataract surgery referrals from optometrists	32%	7%	Received a higher percentage (25% higher) of optometric referrals
Patients always examined by the ophthalmologist prior to the day of surgery	14 (88%)	41 (98%)	
Patients examined by the ophthalmologists the day after surgery (24 hr. exam)	14 (88%)	41 (98%)	
Length of follow-up by the ophthalmologists:			Follow their patients for a shorter time after surgery
(a) one week or less	3 (19%)	0	
(b) 2-4 weeks	2 (13%)	0	
(c) 5-7 weeks	2 (13%)	4 (10%)	
(d) 8 weeks	9 (56%)	38(90%)	
Dollars paid to the sampled ophthalmologists during FY 1987	$30,627,042	$39,155,850	28% of the physicians collected 44% of the total Medicare payments for physicians sampled.
Average payment	$ 1,914,190	$ 932,282	

Total: $69,782,892 paid to the 58 sampled physicians

APPENDIX 7

APPROPRIATE CARE FOR CATARACT SURGERY PATIENTS BEFORE AND AFTER SURGERY

Issues of Medical Safety and Appropriateness

Staff Paper
prepared by the

Health Program
Office of Technology Assessment
U.S. Congress

October 1988

The views expressed in this Staff Paper do not
necessarily represent those of
the Technology Assessment Board, the Technology Assessment
Advisory Council, or their individual members.

OTA Project Staff

Kerry B. Kemp, Study Director (from August 1988)
Barbara Boardman, Study Director (through July 1988)

Other Contributing Staff

Gloria Ruby, Senior Analyst

Clyde Behney, Program Manager, Health Program

Roger Herdman, Assistant Director, Health and Life Sciences Division

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Figure

1. The Human Eye

SUMMARY

In 1976, a study by the U.S. Department of Health, Education, and Welfare addressed the issue of what services to cataract patients were appropriately provided by optometrists (U.S. DHEW, 1976). This OTA Staff Paper, prepared at the request of the Subcommittee on Health of the House Committee on Ways and Means, reconsiders some aspects of that topic in light of some technological changes, legal changes, and other changes that have occurred in cataract surgery during the past decade.

Traditionally, the ophthalmologist who performs cataract surgery on a patient is responsible not only for the surgery itself but for a preoperative assessment to evaluate the patient's fitness for surgery and for postoperative care during the healing process.[1] In the past several years, the traditional model of perioperative care for cataract surgery patients has been challenged as a consequence of changes in technology and legal and other changes in Medicare coverage and reimbursement.

- Changes in surgical techniques have reduced the risks of cataract surgery, and more than 90 percent of cataract surgery patients now have cataract surgery in outpatient settings rather than in the hospital.[2] For patients who now have cataract surgery in outpatient settings such as hospital outpatient departments, surgicenters, or private offices, postoperative care that would once have been given to them by their ophthalmic surgeon while they were recovering from surgery in the hospital can now be given in outpatient settings.
- Two Federal laws have changed the definition of "physician" in the Social Security Act to expand the range of services that optometrists can receive reimbursement for under Medicare. Section 937 of the Omnibus Budget Reconciliation Act of 1980 (OBRA-80, Public Law 96-499) changed the definition to allow optometrists to be reimbursed by Medicare for any Medicare-

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[1] As normally defined, preoperative care is the process of examining and performing diagnostic tests on a patient to assess a patient's fitness for surgery. Postoperative care, which begins with completion of a surgical procedure and continues until the patient's wound has healed, is the process of patient management following surgery that is necessary to ensure the best possible surgical outcome. Throughout this Staff Paper, OTA uses the terms preoperative care and postoperative care specifically in these ways to refer to care before and after cataract surgery. Perioperative care encompasses both preoperative and postoperative care.

[2] Currently, 96 percent of Medicare cataract surgery is done in outpatient settings (Ahern, 1988).

covered service related to the condition of aphakia[3] providing that the performance of that service by optometrists was authorized by the State in which the optometrist practiced. Section 933 of the Omnibus Budget Reconciliation Act of 1986 (OBRA-86, Public Law 99-509) changed the definition to allow optometrists to be reimbursed for all Medicare-covered services that optometrists are authorized to perform by the State in which the optometrist practices.[4] Under OBRA-80 and even more under OBRA-86, optometrists in some States began billing Medicare carriers for postoperative services related to cataract surgery (Mitchell, 1988).

- Since 1986, the Health Care Financing Administration (HCFA) has issued several sets of instructions to Medicare carriers that have been interpreted as sanctioning Medicare payment to optometrists for postoperative services related to cataract surgery. Medicare carriers generally pay a "global fee" for cataract or other surgery. A global fee typically covers the presurgical evaluation of the patient, the surgery itself, and the postoperative followup visits. HCFA has established a billing procedure that some carriers have used to allow the splitting of a global fee between an ophthalmologist who provides cataract surgery and an optometrist who provides followup care (Mitchell, 1988).

The tradition that a surgeon is responsible for the preoperative and postoperative care of a surgical patient has a long history in medicine. According to the principles of the American College of Surgeons: "The responsibility of a surgeon includes preoperative diagnosis and care, the selection and performance of the operation, and postoperative surgical care" (Am. College of Surgeons, 1985). This OTA Staff Paper considers the medical safety and appropriateness of arrangements under which an ophthalmologist performs cataract surgery on a patient and an optometrist at a site separate from the ophthalmologist provides either the preoperative visit to evaluate a patient's fitness for surgery or several of a patient's postoperative visits.

OTA found no scientific studies of patient outcomes when optometrists provide preoperative or postoperative care for cataract surgery patients. Consequently, direct comparisons between the quality of perioperative care provided by ophthalmologists and optometrists could not be made.

In the absence of scientific studies of the outcomes associated with alterations in the traditional model of perioperative care for cataract surgery patients, conclusions about the medical wisdom of giving optometrists an expanded role in the provision of preoperative or postoperative care for cataract surgery patients have to be based on considerations of:

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[3] Aphakia, the absence of the natural crystalline lens of the eye, is a condition that may be present from birth or be caused by surgical removal of the lens (e.g., in the course of cataract surgery). A person who has just had cataract surgery and is in the unstable postoperative period is technically aphakic, although many would argue that such a patient is receiving services for cataract rather than aphakia.

[4] A survey of State laws pertaining to the practice of optometry is available from the American Optometric Association (American Optometric Association, November 1987). Most State optometry laws do not specifically authorize or prohibit the provision of "preoperative or postoperative care related to cataract surgery"; rather, each law specifically allows or prohibits various drugs and procedures that might be employed in such care.

1. the nature of possible postoperative complications after cataract surgery and the skills that may be needed to help prevent or manage those complications,
2. differences in the education and training of optometrists and ophthalmologists that might affect the quality of care the two types of professionals are able provide to cataract surgery patients in the perioperative period,[5] and
3. general models for the provision of postoperative care by someone other than the attending surgeon.

Cataract surgery patients may develop any of several types of postoperative complications. Some of the more common ocular complications can interfere with vision but do not have to be dealt with immediately. On the other hand, there do exist a few rare ocular complications (e.g., endophthalmitis,[6] expulsive intraocular hemorrhage, severe wound rupture) that have to be dealt with immediately to prevent the loss of an eye. A number of other ocular complications are not emergencies like these but are very serious and can destroy an eye if not properly managed (e.g., corneal edema, secondary glaucoma, detached retina) (Jaffe, 1984). Systemic complications following cataract surgery are rare but do occasionally arise, especially in patients with pre-existing diseases such as diabetes or hypertension. Given the volume of cataract surgery performed, more than one million procedures per year, even a relatively small percentage of complications could reflect thousands or tens of thousands of patients.

To minimize the likelihood that serious ocular or systemic complications will occur or become unmanageable requires good preoperative and postoperative care. In the preoperative period, a patient must be evaluated to determine whether cataract surgery is a justifiable risk given the state of the patient's cataract, health of the patient's eyes, and the patient's overall health; which cataract extraction procedure to use and whether to implant an intraocular lens (IOL); and whether the surgery should be done in the hospital or can safely be done in an outpatient setting. Such judgments should be based in part on knowledge of how concurrent eye or systemic disease affects the risks and potential complications of cataract surgery, as well as familiarity with various surgical techniques and IOLs.

In the postoperative period, a cataract surgery patient should be monitored for the development of any ocular or systemic complications. Some of the ocular complications associated with cataract surgery occur in the general population, but others occur primarily as complications of cataract or other surgery. A person who has been trained to perform eye surgery and has had clinical training in the postoperative management of eye surgery patients would probably be better able to recognize such complications than an individual without such training. Furthermore, a number of postoperative ocular complications in cataract surgery patients are associated with certain types of surgical procedures or IOLs or with certain types of problems during surgery. The surgeon who operates on a patient might be more alert to the possibility of these types of complications than someone who is not familiar with the specific procedure the patient underwent or was not present during surgery.

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[5] A recent OTA report on indicators of the quality of medical care found that physicians practicing in the area of their training are likely to deliver higher quality care than others (U.S. Congress, OTA, 1988). The same report found that malpractice compensation was not a reliable or valid indicator of quality.

[6] Endophthalmitis is a severe, sometimes painless, intraocular infection that may be caused by any of a variety of bacterial and fungal agents. The infection may cause a violent inflammatory reaction in the eye and can produce loss of vision if emergency treatment with systemic antibiotics, surgery, or other means is not initiated at once (Deutsch and Goldberg, 1984; Mauriello et al., 1983; Jaffe, 1984).

In almost all instances, the management of the ocular complications that arise after cataract surgery requires difficult judgments about whether and when to use a wide assortment of medical and/or surgical procedures (Jaffe, 1984). The treatment of endophthalmitis and numerous other ocular complications requires the use of antibiotics, steroids, and/or other systemic medications that have to be prescribed by a physician (Jaffe, 1984).[7] The treatment of an expulsive hemorrhage, a detached retina, and several other ocular complications involves major eye surgery that only an ophthalmologist is trained to perform. The management of endocrinologic, cardiac, or other systemic complications may necessitate the involvement of an internist, cardiologist, or other physician.

The education and training of ophthalmologists differ in several important respects from the education and training of optometrists. Ophthalmology is a surgical specialty of medicine, and ophthalmologists must spend 4 years in medical school, 1 year as an intern in a hospital, and 3 years as a hospital-based ophthalmology resident. Optometry is not a specialty of medicine, and optometrists undergo a 4-year professional training program.

As a physician, an ophthalmologist gets 3 years of clinical training (2 years as a medical student and 1 year as a hospital intern) in the evaluation and treatment of patients with a variety of medical conditions. This experience may enable an ophthalmologist to evaluate a patient's fitness for surgery, taking into account the patient's systemic conditions. This experience may also enable an ophthalmologist to initiate management of postoperative complications that require certain systemic drugs or surgery. At no point during training does an optometrist receive clinical training in the evaluation and treatment of patients with a range of medical problems.

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[7] Most States permit optometrists to use certain drugs, under certain conditions, to diagnose eye disease, and 23 State laws permit optometrists to use certain drugs, under certain conditions, to treat selected eye problems (Hibbs, 1987; Mays, July 8, 1988). In no States, however, are optometrists licensed to use the full range of drugs that might be needed to manage the various complications of cataract surgery.

As an ophthalmology resident, an ophthalmologist gets 3 years of clinical training in the evaluation and treatment of patients with serious eye problems. An optometrist gets clinical training in the evaluation of patients for refraction but significantly less experience in the management of patients with serious eye problems. Finally, an ophthalmology resident performs cataract and other eye surgery and manages the postoperative care of many of the patients on whom he or she operates. An optometrist gets considerably less clinical exposure to patients who have undergone eye surgery.

Given the differences in training of ophthalmologists and optometrists just mentioned, it is the assessment of OTA that a preoperative evaluation to assess a cataract patient's fitness for cataract surgery must be done by the ophthalmologist who is to perform the surgery. The preoperative evaluation by an ophthalmologist should take into account not only the state of the cataract and general health of the patient's eye but any systemic problems the patient has that could affect risks and benefits of surgery. The information that is gathered during during a preoperative evaluation can affect the preoperative and postoperative management of a patient and the eventual outcome of the surgery itself.

A greatly expanded role for optometrists in the provision of postoperative care for cataract surgery patients--especially if the care is provided at sites that are geographically separate from the attending ophthalmologist--would represent a significant departure from the traditional model of care for such patients. Though the risks of an expanded role for optometrists have not been measured, several potential risks can be hypothesized:

1. If an optometrist or other caregiver who is not familiar with the specifics of a particular patient's cataract surgery provides postoperative care, continuity of care and the resulting quality of care may be adversely affected.
2. Optometric training may not give optometrists sufficient clinical exposure to the postoperative management of cataract surgery patients to enable them to make physical exams consistent with those of an attending ophthalmologist or to fit their exams into a regimen of postoperative patient management.
3. If a cataract surgery patient develops an ocular complication that requires the involvement of the attending ophthalmologist (e.g., to prescribe drugs that have to be prescribed by a physician or to perform further eye surgery), a delay of several hours may occur before appropriate treatment is initiated, because few optometrists have 24-hour, weekend, on-call, or emergency services for their patients. In some cases (e.g., those involving endophthalmitis, expulsive hemorrhage), a delay of several hours could result in the loss of an eye or other serious problems.

In spite of the absence of a known risk, cautious medical practice suggests we should be aware of the potential risks of giving optometrists an expanded role in providing postoperative care for cataract surgery patients and make reasonable efforts to address the concerns that have been raised. Moving away from the traditional model of care without a scientific assessment of the likely effects on patient outcomes runs the risk of reducing the quality of care that cataract surgery patients receive. A more prudent approach would be to allow cautious alterations in the traditional model--alterations that attempt to address plausible hypothesized concerns about quality--and then to evaluate the effects.

INTRODUCTION

Cataract surgery is one of the most common procedures performed on the Medicare population. Traditionally, the attending surgeon--an ophthalmologist--is responsible for performing a preoperative evaluation of a patient's fitness for cataract surgery, for performing the cataract surgery, and for managing a surgical patient's postoperative care (Jaffe, 1984). In the last several years, the nature of cataract surgery itself has changed, and legal and other changes in Medicare payment have led some optometrists and ophthalmologists to challenge the traditional model of perioperative care for cataract surgery patients. This OTA Staff Paper evaluates the medical safety and appropriateness of an expanded role for optometrists in the preoperative and postoperative management of cataract surgery patients. OTA was asked to prepare the Staff Paper by the Subcommittee on Health of the House Committee on Ways and Means.

In a sense, this OTA Staff Paper is an update of a 1976 study conducted for Congress by the U.S. Department of Health, Education, and Welfare (HEW)[8] (see app. A for a summary). The question examined in the 1976 study was: What services related to aphakic and cataract conditions that are reimbursable under Part B of Medicare when provided by a physician (e.g., an ophthalmologist) are appropriate for reimbursement when provided by an optometrist (U.S. DHEW, 1976). The findings of the 1976 study, though comprehensive for the time, do not address several issues pertaining to medical safety and appropriateness of optometric involvement in perioperative care for cataract surgery patients as might be contemplated in 1988.

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[8] In 1979, the Department of Health, Education, and Welfare (HEW) was separated into two components: the U.S. Department of Health and Human Services and the U.S. Department of Education.

One of the conclusions of the 1976 study was that optometrists were qualified to provide a broad range of services beyond refraction and the provision of eyeglasses (U.S. DHEW, 1976). According to the 1976 study, the initial diagnostic visit and any visits for cataract care before surgical intervention is suggested were within the competence of an optometrist. Such visits do not constitute preoperative care as traditionally defined to include the evaluation of a patient's fitness for surgery.

Not surprisingly, the 1976 study drew no specific conclusions with respect to the appropriateness of expanding optometric involvement in the postoperative care of cataract surgery patients. In 1976, unlike today, cataract surgery was a surgical procedure that was virtually always performed in the hospital. Optometric involvement in postoperative care for cataract surgery patients in the hospital would have run counter to all legal and hospital regulations and was therefore not even discussed in the 1976 report.

In its recommendations pertaining to the extension of Medicare Part B reimbursement to optometrists, HEW distinguished between services for aphakia and services for cataract conditions.[9] HEW recommended the extension of Part B Medicare reimbursement to optometrists for services related to aphakia that were authorized by State optometric scope of practice laws[10] and against the extension of Part B reimbursement coverage for Medicare-covered services provided by optometrists to cataract patients prior to surgery. The extension of reimbursement for optometrists' services provided prior to cataract surgery, HEW said, should await resolution of issues that were not addressed by the 1976 study (e.g., development of an operational definition of cataract, patient health care implications, cost implications, delivery pattern changes, appropriate patient cost sharing).

Since the time of the HEW study, there have occurred technical, legal, and regulatory changes that, according to some observers, argue for an expansion in the traditional role of optometrists in the perioperative care of cataract surgery patients. The medical safety and appropriateness of moving away from the traditional model of perioperative care for cataract surgery patients is addressed in the discussion that follows.

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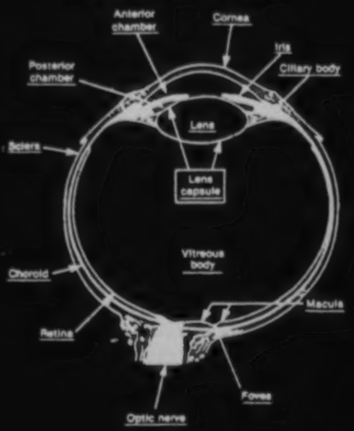
[9] Aphakia, the absence of the natural lens of the eye, is a condition that may be caused by surgical removal of the lens in the course of cataract surgery.. Whether a person who has just had cataract surgery and is in the immediate, unstable postoperative period remains a "cataract patient" or, having had the lens removed, is now an "aphakia patient" is a matter of opinion.

[10] HEW's recommendation with respect to extending Medicare Part B reimbursement to optometrists' services for aphakia was incorporated in Section 937 of the Omnibus Budget Reconciliation Act of 1980 (Public Law 96-499, OBRA-80), discussed later in this Staff Paper.

CATARACTS: CAUSES AND PREVALENCE

A cross section of a normal human eye is depicted in figure 1. In a normal eye, a clear crystalline lens behind the pupil serves to focus light on the retina, which will ultimately receive the image and transmit it to the brain. The natural lens of an adult eye is about 10 mm (.39 inches) in diameter and approximately 4 mm thick. It is enclosed by a transparent membrane called a lens capsule that is 11 to 18 microns (0.0004 to 0.0007 inches) thick (Bloom and Fawcett, 1975). An opacity of the normally clear lens or of the lens capsule that encases the lens is known as a cataract. Typically, a cataract develops over time. As a cataract "matures" (progressively becomes more opaque), a person experiences a slow progressive loss of vision.

Figure 1.—The Human Eye



Cataracts are a major cause of visual impairment (trouble seeing even with glasses) in the U.S. population. According to data from the National Society To Prevent Blindness[11] cited by the Cataract Panel of the National Eye Advisory Panel, 35 percent of existing visual impairments and 53 percent of new cases of visual impairments are due to cataracts[12] (U.S. DHHS, PHS, 1987). Untreated, cataracts progress to the point where they cause blindness (Jaffe, 1984). Cataracts are the third leading cause of legal blindness in the United States (U.S. DHHS, PHS, 1987).

By far the most common type of cataract is senile (or senescent) cataract (U.S. DHHS, PHS, 1987). Senile cataracts are thought to be caused by alterations in the lens that are associated with increasing age (Jaffe, 1984). Other causes of cataract include diabetes mellitus and other metabolic disorders, toxic environmental agents such as radiation, trauma, infection, and congenital malformation (U.S DHHS, PHS, 1987).

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[11] The data from the Society To Prevent Blindness involve 1970 numbers projected to 1980.
[12] These statistics should be used with caution, because the data are old and predate the more recent development of more successful treatment of cataract.

Table 1 shows data on the prevalence of cataracts from the 1975 Framingham eye study (U.S. DHHS, PHS, 1987) and from the 1982 National Health Interview Survey conducted by the National Center for Health Statistics (LaPlante, in press). Although the data from the 1975 Framingham eye study are somewhat old, they do show the prevalence of cataract for the population over age 65. More recent data from the National Health Interview Survey show similar prevalence rates.

Table 1.--Prevalence of Cataract by Age Group
(cases per 1,000 people)

	52-64 yrs	65-74 yrs	75-85 yrs
Framingham Eye Study (1975):			
Lens opacity:			
Men	37.9	68.1	88.2
Women	44.7	76.7	93.0
Cataract:			
Men	4.3	16.0	40.9
Women	4.7	19.3	48.9

	45-69 yrs	70-84 yrs
Nat. Health Interview Survey (1982):		
Cataract:		
Males	24.6	112.9
Females	34.6	217.6

SOURCES: **Framingham data:** U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Vision Research: A National Plan--Report of the Cataract Panel, NIH Pub. No. 84-2473 (Bethesda, MD: 1987).
National Health Interview Survey data: M. LaPlante, "Data on Disability From the National Health Interview Survey, 1983-85," prepared for the National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC, in press.

The data in table 1 give an indication of the prevalence of cataracts before the large increase in cataract surgery that has occurred in the 1980s. As the numbers in that table show, cataracts occur with high frequency in older populations, and the phenomenon increases with age. Thus, as the number of elderly people increase, the absolute number of people with cataract is likely to increase.

The only effective treatment for cataract, cataract surgery, is described below. Cataract surgery can be performed at various points in the maturation of the cataract, depending, for example, on judgments about the extent to which the cataract interferes with the patient's life. A general shift to earlier surgery would increase the absolute number of procedures done (see discussion below).

CATARACT SURGERY: THE TECHNOLOGY

Cataract surgery--resorted to when a cataract becomes visually disabling--involves the removal of the clouded natural lens of the eye through an incision in the cornea or sclera (white part of the eye) (U.S. DHHS, PHS, 1987). As described below, the surgery may involve various methods, the most common of which are intracapsular extraction methods and extracapsular extraction methods (U.S. DHHS, PHS, 1987). Following extraction of the cataract, the surgical incision is closed by sutures (stitches), which may or may not need to be removed.

To regain vision after the natural lens has been removed, the patient must receive some type of prosthetic (artificial) replacement lens. The replacement may involve either an intraocular lens (IOL) implanted at the time of surgery or afterward, a contact lens, cataract eyeglasses, or some combination of these, depending on factors such as the patient's ability to wear a contact lens, the refractive status of the patient's other eye, and the age of the patient. In 1987, IOLs were placed in 85 percent of cataract procedures (Reuter and O'Sullivan, 1987). IOLs are not without certain problems, but they do offer several optical and other advantages over cataract glasses and contact lenses (U.S. DHHS, PHS, 1987). Furthermore, IOLs are generally preferred in the case of elderly patients, many of whom may have trouble manipulating and adapting to contact lenses (Jaffe, 1984).

Increasing Use of Posterior Chamber IOLs

IOLs have undergone continuous evolution in design, weight, and manufacturing processes since their introduction after World War II (U.S. DHHS, PHS, 1987). The first truly successful IOLs were anterior chamber IOLs, lenses placed in the anterior chamber of the eye, under the vault of the cornea, and in front of the iris (Safir, 1983). The pressure of an anterior chamber lens against the tissues holding it sometimes causes disturbances that can be serious (Safir, 1993), and in recent years, posterior chamber IOLs have been rapidly gaining in popularity over anterior chamber IOLs. Posterior chamber IOLs are lenses placed in the posterior chamber, the place behind the iris from which the patient's own natural lens has been removed (Safir, 1983). From an optical point of view, the posterior chamber is the desirable place to put an IOL (although the undesirable long-term effects of posterior chamber lenses have probably not all become evident yet) (Safir, 1983).

In 1983, 48 percent IOLs placed were posterior chamber IOLs and 45 percent were anterior chamber IOLs (the remaining 7 percent were iridocapsular or iris fixation IOLs) (Stark et al., 1983). From February 1987 to February 1988, 91 percent of IOLs placed were posterior chamber IOLs and 9 percent were anterior chamber IOLs (Stark, 1988).

Advances in Surgical Techniques[13]

In recent decades, improvements in the techniques of cataract surgery and the implantation of IOLs have made cataract surgery one of the safest and most successful of all major operations (U.S. DHHS, PHS, 1987). Despite some of the advances, which are discussed further below, however, significant postoperative complications may occur in patients who undergo this surgery (U.S. DHHS, PHS, 1987).

Improved techniques in cataract surgery were made possible by improvements in preoperative medications, operative anesthesia, operating microscopes, and various microsurgical instruments (Safir, 1983). By the mid-1960s, the operation of choice for cataract removal was a technique known as intracapsular cataract extraction (Safir, 1983). The intracapsular technique involves removing both the natural crystalline lens of the eye and all of its surrounding capsule. Following an intracapsular cataract extraction procedure, the patient usually gets an anterior chamber IOL.

If a patient's lens is removed by the intracapsular extraction technique, an IOL placed in the posterior chamber will be resting against the vitreous body and may easily dislocate and slide down onto the retina, where it can do harm and be inaccessible to surgical removal (Safir, 1983). Consequently, surgeons choosing to put IOLs in the posterior chamber have revived interest in a technique known as extracapsular cataract extraction, which leaves the posterior portion of the lens capsule in place to support the IOL (Safir, 1983). Extracapsular extraction, by preserving the biologic separation of the vitreous body from the anterior chamber, decreases the risk of a vision-threatening complications such as as aphakic retinal detachment,[14] bullous keratopathy,[15] or cystoid macular edema.[16]

Until recently, intracapsular extraction was the preferred method of extraction, because the extracapsular extraction technique was difficult and left lens fragments in place that impaired the patient's vision. Since the development of posterior chamber IOLs (Reuter and O'Sullivan, 1987) and improved surgical techniques that permit an ophthalmologist to perform an extracapsular extraction without leaving lens fragments behind, extracapsular extraction has gained in popularity. As of 1987, the vast majority (93.5 percent) of lens extractions were extracapsular extractions (Sanders, 1987).

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[13] For those who are interested, much of this discussion was drawn from "How Ophthalmology Has Changed During My Career," a fascinating paper on technological and other changes in ophthalmology prepared for OTA in 1983 by A. Safir.

[14] Aphakic retinal detachment is the detachment of the retina which occurs in association with the loss or absence of a lens and may be physiologically related to removal of the lens.

[15] Bullous keratopathy is a noninflammatory disease of the cornea.

[16] Cystoid macular edema is a condition that involves swelling in the macula, which is the very highly specialized part of the retina that is responsible for fine, high-resolution, central vision acuity (Safir, 1983). The accumulation of fluid in the macula causes blurring of vision and may result in loss of central vision.

Innovations in the techniques of cataract surgery are continuing. Microchip technology has permitted the development of a new technique for removing a natural lens called phacoemulsification. In phacoemulsification, the natural lens is ultrasonically fragmented and then is removed through a small (3 mm) incision (Nevyas, 1986). The use of phacoemulsification plus a new foldable silicone or hydrogel IOL will permit much smaller (3 mm as compared to 12 mm) incisions in patients who are candidates for this type of surgery. Smaller incisions in these patients may mean reduced postoperative astigmatism and fewer complications (Nevyas, 1986). Although only 13.2 percent of cataract extractions in 1987 involved phacoemulsification, the use of this technique is increasing (Sanders, 1987). Currently, the use of the newest types of IOLs--soft, foldable IOLs--is associated with slightly higher complication rates, including postoperative inflammation and occasional lens extrusion[17]; over time, however, outcomes with foldable lenses may be expected to improve (Sanders, 1987).

How Advances in Technology Have Altered Cataract Surgery

The development of more advanced technologies, including microsurgical techniques and instruments, has altered the nature of cataract surgery in several ways. First, the technical training required for doing cataract surgery has increased, and the equipment required for treatment is considerably more complex. Second, the precision and predictability of cataract surgery have improved considerably. Improved vision now occurs in the vast majority (94 to 96 percent) of cataract patients who undergo surgery (Allen and Hui-rong, 1987; Ruther and Black, 1987; Stark et al., 1983). Third, the medical risk of cataract surgery to the patient has decreased (Jaffe, 1984). Finally, because of improvements in techniques, cataract surgery today involves a much shorter hospitalization or is done on an outpatient basis (Jaffe, 1984). In 1966, the average length of stay for cataract surgery was 7.6 days; in 1977, it was 4.8 days; and in 1984, it was 2.1 days for those having inpatient surgery (Reuter and O'Sullivan, 1986). Currently, 96 percent of Medicare cataract surgery is done on an ambulatory basis (Ahern, 1988).

Increasing Number of Procedures

In recent years, the absolute number of cataract removal procedures has increased (Biomedical Business International, 1987; Sanders, 1987). Although there is some disagreement as to the exact number of cataract removal procedures are performed today, there is a consensus that cataract removal procedures are being done at an increasing rate. In 1983, approximately 700,000 cataract extractions were performed and 500,000 IOLs were implanted in the United

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[17] Lens extrusion is displacement of the lens from the posterior chamber.

States (Jaffe, 1984). Biomedical Business International reports 1.1 million IOLs were placed in 1987 and projects that the market for such lenses will grow at a rate of 7 percent per year to 1990; since IOLs are placed in the large majority of patients who undergo cataract surgery, the increasing market for IOLs reflects growth in the number of cataract removal procedures (Biomedical Business International, 1987). Sanders estimates that 1 million cataract removal procedures will be performed in 1988 (Sanders, 1987).

What accounts for the increasing performance of cataract surgery is not entirely clear. Some might argue that because of improvements in surgical techniques that have reduced the risks of cataract surgery and allowed the shift of cataract surgery from hospital to ambulatory settings, the decision about whether to perform cataract surgery may be more likely to be made in favor of surgery now than it was in the past. The decision about whether to perform cataract surgery, like all medical decisions, should involve consideration of the risks and the benefits for a particular patient. The decision should be influenced by: 1) how severe a patient's cataract is, 2) how debilitating the cataract is for the patient when his or her particular life situation is considered, and 3) how the risks of cataract surgery weigh against the benefits for the particular individual. With technical improvements and decreased risks associated with the cataract extraction procedure plus improved visual rehabilitation of patients receiving IOLs, the balance of this equation may have tipped toward surgical extraction for more patients. Another view, however, is that the increasing number of surgical procedures may result in part from reduced thresholds for the performance of cataract surgery brought about by an overabundance of ophthalmologists (Greenberg, 1988; Trobe and Kilpatrick, 1983).

MEDICARE POLICIES: RECENT CHANGES THAT AFFECT CATARACT CARE

In 1980 and 1986, Congress amended the definition of "physician" in the Social Security Act to enlarge the scope of vision services that optometrists can receive reimbursement for under

Medicare, while at the same time it recognized the preeminence of States in establishing and controlling optometrists' scope of practice.[18] In 1986 and 1987, the Health Care Financing Administration (HCFA) issued instructions to Medicare carriers[19] to clarify how Medicare would pay for surgical care when the postoperative or other services related to surgery are provided by someone other than the attending surgeon. These laws and instructions, discussed further below, have been interpreted by some Medicare carriers in such a way as to allow optometrists to bill for postoperative services to cataract surgery patients. Especially since 1986, optometrists have been increasingly billing Medicare for postoperative services related to cataract surgery (Marsalek, Aug. 24, 1988).

Recent Changes in the Social Security Act and Regulations

In 1980, Congress amended the Social Security Act to expand the range of vision services optometrists could provide and receive payment for under Medicare via Section 937 (Optometrists' Services) of the Omnibus Reconciliation Act of 1980 (OBRA-80, Public Law 96-499). Section 937 of OBRA-80 eliminated a provision of the Social Security Act limiting Medicare payment to optometrists to payment for "establishing the necessity for prosthetic services" and replaced it with a provision limiting Medicare payment to optometrists to payment for "services related to the condition of aphakia" (Sec. 937 (a)).[20] Aphakia was defined in the Code of Federal Regulations as "the absence of the natural crystalline lens of the eye, regardless of whether an intraocular lens has been implanted" 42 CFR 410.23 (10-1-87 ed.). Section 937 provision became effective July 1, 1981 (Sec. 937 (c)).

Federal regulations implementing Section 937 specified that if the services were related to aphakia and authorized by the State in which the optometrist practiced, an optometrist could receive Medicare reimbursement for "examination services" including case history, external examination, ophthalmoscopy,[21] biomicroscopy,[22] tonometry,[23] evaluation of fields of vision, evaluation of ocular motility, evaluation of binocular function, and examinations required to prescribe prosthetic lenses in connection with aphakia (42 CFR 410.23 (10-1-87 ed.)). During the period 1980 through 1986, relatively few optometrists billed Medicare directly for the postoperative care of cataract surgery patients, but it was common in some areas for an ophthalmologist who used an optometrist's services for postoperative care of a patient to bill Medicare for the full global fee for the surgery and then pay the optometrist directly for the followup services (Mitchell, 1988).[24]

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[18] Some services are specifically excluded from Medicare coverage, regardless of whether they are performed by doctors of medicine, osteopathy, or optometry and regardless of whether they are authorized by a State. Exclusions include: 1) routine eye examinations not performed to diagnose a specific symptom or complaint, and 2) eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive errors (as opposed to prosthetic lenses required by an individual lacking the organic lens of the eye).

[19] Part B of the Medicare program is administered on a day-to-day basis through contracts negotiated between the Federal Government and State-based health insurance carriers. It is the responsibility of the carriers to apply policies regarding benefits and limitations in accepting or rejecting bills submitted for reimbursement and to determine that charges made for covered services are reasonable (U.S. DHEW, 1976).

[20] OBRA-80 put into effect HEW's 1976 recommendation (U.S. DHEW, 1976) that Medicare Part B reimbursement be extended to optometrists for services related to aphakia (see app. A). OBRA-80 also called upon the U.S. Department of Health and Human Services to submit to Congress by January 1, 1982, legislative recommendations with respect to Medicare reimbursement for "services furnished by optometrists in connection with cataracts and such other services as they are legally authorized to perform."

[21] Ophthalmoscopy is the inspection of the internal structure of the eye using illumination and magnification.

[22] Biomicroscopy is the inspection of frontal tissues of the eye using illumination and magnification.

[23] Tonometry is the measurement of the internal pressure of the eye.

In 1986, Congress amended the Social Security Act via Section 9336 (Vision Care) of the Omnibus Reconciliation Act of 1986 (OBRA-86, Public Law 99-509). Section 9336 of OBRA-86 expanded the services that an optometrist could be reimbursed for by Medicare to include all services covered by Medicare "which he is legally authorized to perform as a doctor of optometry by the State in which he performs them. . . ." (Sec. 9336 (a)). This provision became effective April 1, 1987 (Sec. 9336 (b)). Since that time, HCFA has issued several instructions giving guidance to Medicare carriers on dealing with Medicare claims procedures and reasonable charges under the provision.

Recent Changes in Instructions to Medicare Carriers

Since 1986, HCFA has issued several sets of instructions to Medicare carriers that have been interpreted as sanctioning Medicare reimbursement to optometrists for postoperative services related to cataract surgery. Medicare carriers generally pay a "global fee" for cataract and other surgery. The global fee typically covers the presurgical evaluation of the patient, the surgery, itself, and the postoperative followup visits (Mitchell, 1988). HCFA's carrier instructions, summarized below, established billing procedures that some carriers have used to allow the splitting of a global fee for cataract surgery between an ophthalmologist who performs cataract surgery and an optometrist who provides followup care. An ophthalmologist billing these carriers places the modifier "-54" at the end of the surgical procedure code to indicate that his or her bill is only for the surgery and does not include postoperative care; the optometrist who provides postoperative care adds the related modifier "-55" to indicate that his or her bill is for postoperative services only (Mitchell, 1988). The Medicare carrier reduces the global payment to the ophthalmologist by an established percentage (ranging from 5 to 30 percent at different carriers) of the normal global fee for surgery, and the difference (or some other amount) goes to the optometrist who performs the followup visits (Mitchell, 1988).

In March 1986, HCFA issued an instruction to Medicare carriers to clarify how Medicare would pay for surgical care when the surgery and related services are provided by more than one physician. That instruction, summarized below, was a general instruction that did not specifically pertain to cataract surgery.

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[24] In a case in North Carolina, an ophthalmologist billed the Medicare carrier (Prudential) a global fee for cataract surgery and then paid the optometrist who provided postoperative care out of pocket (Marsalek, Aug. 24, 1988). The Inspector General's Office did not approve of this, and on January 13, 1986, the carrier issued instructions that called for separate billing and procedure codes by the operating ophthalmologist and the optometrist who provided routine post-cataract-surgery care (the surgeon was to use the modifier "-54" with the appropriate surgical procedure code to show that the bill was for the surgery only, and the optometrist was to use the new procedure code W9245) (Prudential Insurance Co., 1986). Subsequently, some optometrists began billing Medicare directly for some postoperative services related to cataract surgery (Marsalek, Aug. 24, 1988).

- Revision 1146, March 1986: "Sec. 5248: Making Reasonable Charge Determinations When Physicians Fragment Previously Global Charges": Many surgeons, including ophthalmologists, typically render preoperative care, the operative care, and the postoperative care related to a surgery and bill Medicare one fee, termed a global fee, for all care. In cases where the care is provided by more than one physician,[25] and if a global fee was in effect in 1973, reimbursement to individual physicians cannot exceed the global prevailing fee adjusted by the economic index (U.S. DHHS, HCFA, March 1986).

Following the enactment of OBRA-86, HCFA issued several additional sets of carrier instructions to help implement the new law and to make its March 1986 instruction specific to services pertaining to cataract surgery. Those instructions are summarized below.

1. Revision 1182, April 1987: "Sec. 2020.25: Optometrists"
   - A. Services Furnished Through March 31, 1987
   - B. Services Furnished After March 31, 1987. As mandated by OBRA-86, Sec. 9336, effective April 1, 1987, a doctor of optometry is considered a physician with respect to all services the optometrist is authorized to perform under State law or regulation.
   - C. General Claims Guidelines. Ophthalmologists performing cataract surgery have historically charged a single global fee that encompasses the presurgical evaluation of the patient, the surgery itself, and the postoperative followup care. Since some of the postoperative services are also covered when furnished by optometrists, the carrier should establish a screening mechanism to identify inappropriate or duplicative services. If an ophthalmologist charges a global fee for cataract surgery but another physician (e.g., an optometrist) furnishes some of the postoperative services, the portion of the global fee that represents services not furnished by the ophthalmologist should be disallowed; and the optometrist who provided the postoperative care should be reimbursed for the allowed services that he or she performs (U.S. DHHS, HCFA April 1987a).

2. Revision 1182, April 1987: "Sec. 5250: Reimbursement for Cataract Glasses, Contact Lenses and Related Services, and Optometrists' Service.
   - A. Cataract Glasses, Contact Lenses, and Related Services

     When postoperative services encompassed by a carrier's global allowance for cataract surgery are performed by someone other than the surgeon, the physician submitting the bill for surgical care only should add the modifier "-54" to the code used for the surgical procedure. The physician who provides covered postoperative services only should add the modifier "-55" to the code for the surgical procedure. In addition, all physicians should be asked to submit to the carrier a narrative description of the care they provided so that the carrier can make appropriate payment determinations (U.S. DHHS, HCFA, April 1987b).

3. Revision 1208, August 1987: "Sec. 5250: Reimbursement for Cataract Glasses, Contact Lenses and Related Services, and Optometrists' Services":
   - B. Other Medical and Health Services Furnished by Optometrists

     Beginning with services furnished on or after April 1, 1987, Medicare will pay for all other covered medical and other health services furnished by a doctor of optometry which are reasonable and medically necessary and which he or she is legally authorized to perform by the State in which he or she practices.
   - C. Use of Charge Data To Determine Reasonable Charges for Optometrists' Services
     1. Customary Charges.
     2. Prevailing Charges.

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[25] Effective July 1, 1981, as a consequence of OBRA-80, an optometrist is considered a "physician" (i.e., eligible for reimbursement) by Medicare when rendering services related to aphakia; and effective April 1, 1987, as a consequence of OBRA-86, an optometrist is considered a "physician" by Medicare when rendering services that optometrists are legally authorized to render by the State in which the optometrist practices.

> 3. Global Allowances. When an optometrist performs covered services that a Medicare carrier ordinarily pays for as part of a global allowance for a surgeon's (e.g., ophthalmologist's) service, the payment amounts should be determined in accordance with the applicable guidelines including Sec. 2020.25.C, which emphasizes the need to avoid making duplicative payments. Consequently, when a carrier pays for an optometrist's covered services in accordance with Sec. 5250B and the services are normally reimbursed through a global allowance for surgery, the total of the separate allowances for the services of the surgeon and the optometrist may not exceed the applicable global prevailing fee for the surgery (U.S. DHHS, HCFA, August 1987).

The interpretation of HCFA's instructions in the case of perioperative care for cataract surgery patients has varied among carriers, who traditionally are allowed great discretion in interpreting instructions from HCFA's central office. At least one Medicare carrier has interpreted the instructions in such a way as to allow individual ophthalmologists to assign some percentage of their global fee for surgery to an optometrist who provides postoperative care (Aetna Life Insurance Co., 1988). In a letter dated May 20, 1988, HCFA's Office of Reimbursement Policy said it prefers that ophthalmologists and optometrists bill separately for their services and that Medicare carriers--rather than providers with possible incentives to give kickbacks for referrals--determine payment amounts (U.S. DHHS, HCFA, May 20, 1988).

Evolving Arrangements for the Delivery of Perioperative Care

Although there have been anecdotal reports of cataract surgery being practiced with extensive optometric involvement in postoperative care (American Optometric Association, August 1988; Hoffman, 1987, 1988a, 1988b; Root, Feb. 15, 1988), systematic evaluations of the nature or extent of optometrists' role in providing preoperative or postoperative care for cataract surgery patients are not available.

The Inspector General's Office of the U.S. Department of Health and Human Services, analyzing preliminary data from a study of postoperative cataract care (involving the examination of payments made on behalf of 1,000 Medicare beneficiaries plus interviews with 58 ophthalmologists and 28 optometrists), found that 97 percent of the payments reviewed involved a global fee for cataract surgery and only 3 percent involved a split fee; however, 28 percent of the ophthalmologists interviewed permit optometrists to provide postoperative care (Mitchell, 1988). Scientifically reviewed evaluations of the role optometrists play in providing postoperative cataract care are currently being worked on by HCFA and the U.S. General Accounting Office (Ahern, 1988; Baugher, May 10, 1988).

Surveys of patterns of practice may help illuminate the nature and extent of cooperative or other arrangements between optometrists and ophthalmologists for the provision of postoperative cataract care. Other useful information might be derived from evaluations of how practice patterns are related to factors such as geographic region or rural vs. urban area and evaluations of the economic costs and incentives for various parties involved.

THE TRADITIONAL MODEL OF CARE FOR PATIENTS UNDERGOING CATARACT SURGERY

Traditionally, the ophthalmologist who performs a patient's cataract surgery is responsible for the patient's care from the preoperative evaluation through the completion of the patient's healing process. An initial diagnostic screen and a postoperative visit for refraction following cataract surgery may be provided by an optometrist. But the ophthalmologist who performs a patient's surgery provides a preoperative evaluation to assess the patient's fitness for cataract surgery and all of the postoperative visits following cataract surgery (except, in some cases, the visit for refraction). A typical course of visits for a cataract surgery patient under the traditional model of care is shown in table 2.

Preoperative Assessment of Cataract Surgery Patients

As noted in table 2, the initial diagnostic evaluation of a patient with a cataract may be done by an optometrist, who then makes a judgment about whether to refer the patient to an ophthalmologist for further evaluation and possible cataract surgery. In deciding whether to refer a patient, the optometrist should perform a thorough eye examination and consider such things as the amount of visual interference the patient experiences, how much the interference is likely to worsen, whether the cataract affects one or both eyes, and the health of each eye; the optometrist should also consider the patient's medical history (Nevyas, 1986). In deciding which ophthalmologist to send a patient to, the optometrist should consider such things as the ophthalmologist's track record and access to equipment needed to ensure a good outcome (Nevyas, 1986).

A referring optometrist or primary care physician may very well use some of the same examinations and diagnostic tests in a diagnostic assessment as an ophthalmologist or other surgeon uses in a preoperative evaluation of a patient. Traditionally, however, the evaluations by the optometrist and the ophthalmologist are separate. The reason is that an ophthalmologist contemplating cataract surgery for a patient needs to gather information to make a variety of preoperative judgments.

In order to make sound preoperative judgments regarding the advisability of cataract surgery for a particular patient, the appropriate surgical procedure, the advisability of implanting an IOL, and the setting in which surgery should be performed, the ophthalmologist should perform a preoperative evaluation to assess:

- the effect of the cataract on the patient's vision and lifestyle,
- the overall health of the patient's eye, and
- the patient's general health.

Table 2.--Typical Course of Visits for a Cataract Surgery Patient Under the Traditional Model of Care

	Purpose/concerns	Procedures used
Initial diagnostic screen*	To detect cataract	Diagnostic procedures to detect cataract, evaluate eye health
Preoperative surgical evaluation	To assess need and fitness for for cataract surgery	Diagnostic procedures to diagnose cataract, evaluate eye health; gather information about systemic health
Surgery	To remove cataract	Surgery
Postoperative visits	To optimize surgical outcome	Diagnostic and therapeutic procedures (e.g., prescribe or administer drugs, perform surgery)
Day 1	Inflammation Infection Secondary glaucoma Bleeding Wound leaks	
Day 3-5	Infection Secondary glaucoma Bleeding Wound leaks	
Week 2-3	Delayed infection Retinal disease Suture-induced astigmatism	
Week 6	Suture-induced astigmatism	
Week 6-12*	Final refraction	Prescription for corrective lenses

*NOTE: Traditionally, the visits for the initial diagnostic screen and for refraction following cataract surgery may be provided by either an optometrist or an ophthalmologist. All the other visits are provided by the ophthalmologist who performs a patient's surgery.

SOURCES: American Optometric Association, Alexandria, VA, personal communication, August 1988; N.S. Jaffe, Cataract Surgery and Its Complications, 4th ed. (St. Louis, MO: C.V. Mosby Co., 1984); H.R. Stokes, Secretariat for Governmental Relations, American Academy of Ophthalmology, Florence, SC, personal communication, Aug. 9, 1988; and I.G. Wong, Kaiser Permanente Medical Care Program, Northern California Region, Redwood, CA, personal communication, Apr. 2, 1988.

The severity of visual loss from a cataract can be measured in various ways, but the general consensus is that it is not just the loss of visual acuity that should be measured in determining the need for cataract surgery but the cataract's effect on the patient's life functioning (Jaffe, 1984). The overall health of the patient's eye should be assessed by the ophthalmologist for several reasons. One reason is to evaluate the patient's suitability for surgery. In the case of a patient with optic nerve damage behind the cataract or amblyopia,[26] for example, correction of the patient's cataract will not correct the patient's vision problems (Nevyas, 1986). Some ocular conditions (e.g., previous retinal detachment) may be contraindications for implanting an IOL (Jaffe, 1984). Other ocular problems (e.g., ocular structural deformity, corneal disease, extreme myopia, and glaucoma) may alert the ophthalmologist to the possibility of certain complications and affect judgments regarding the appropriate type of surgery to perform and how to manage the patient postoperatively (Coonan et al., 1985; Jaffe, 1984; Sherif and Dardenne, 1981).

The patient's general health should be evaluated by an ophthalmologist to identify serious systemic medical conditions (e.g., heart disease, hypertension, or diabetes) that affect the risks and benefits of surgery for the patient (Jaffe, 1984). In a population of elderly individuals, who are from the age group in which most cataracts occur, the likelihood that concurrent systemic disease is present is fairly high. According to one standard text, systemic conditions seldom preclude the possibility of cataract surgery:

> Cataract surgery has progressed to the point where only rarely need a patient be refused surgery because of physical disability. However, the surgeon must exercise good judgment when considering surgery on feeble aged and infirm individuals. Cataract surgery is usually unjustified on a patient with an overwhelming medical problem such as a terminal stage of malignancy. If an intelligent medical workup is obtained, most temporary contraindications can be eliminated (Jaffe, 1984, p. 5).

If cataract surgery is performed, the information about a patient's general health that is gathered during a preoperative assessment may affect the preoperative, surgical, or postoperative management of the patient. If a patient is severely anemic, has an active peptic ulcer, has uncontrolled colitis, or has uncontrolled diabetes, for example, the problem will have to be corrected prior to surgery (Jaffe, 1984). If a patient is taking anticoagulant medications, the medications will have to be stopped prior to surgery (Jaffe, 1984; Nevyas, 1986). If a patient is a frail elderly person with cardiovascular disease and uncontrolled diabetes or hypertension, a decision may be made to perform cataract surgery in the hospital rather than in a physician's office or other outpatient setting. It is especially important to know whether systemic steroids or antibiotics may be used safely in case of postoperative complications (Jaffe, 1984). In some cases, there may be a need to involve the patient's internist in the patient's preoperative and postoperative care.[27]

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[26] Amblyopia is a condition of poor visual acuity resulting from various congenital and/or developmental abnormalities of the eye.

[27] Ophthalmologists do not themselves always perform presurgical physical examinations. In uncomplicated cases, for example, an intake physical may be performed by the anesthesiologist who has to deal with systemic emergencies during surgery. For patients who have pre-existing conditions that mitigate against the advisability of outpatient surgery, a presurgical physical is almost always handled as a "consult" from "medicine" (internal medicine) (Greenberg, 1988).

Postoperative Care of Cataract Surgery Patients

The purpose of the postoperative care of a cataract surgery patient is to monitor healing and to take whatever steps are necessary to help ensure the best possible surgical outcome. The typical course of postoperative care for cataract surgery patients involves 5 to 10 visits, depending on the problems that arise postoperatively (Jaffe, 1984; Wong, 1988).

Postoperative visits are scheduled to occur at times that will overlap with the peak periods of risk for the complications that are of greatest concern (see table 2). At the first postoperative visit, the attending ophthalmologist performs an evaluation to assess postoperative inflammation and to detect problems such as infection, secondary glaucoma, bleeding, or wound leaks. An eye check is performed on the third to fifth day after surgery, timed to occur when the risk of infection is highest (Stokes, 1988). Between the second and sixth weeks after surgery, checks for suture-induced astigmatism and retinal disease are performed. During each of these postoperative visits, the attending ophthalmologist reassesses medication dosages, adjusts the patient's sutures as deemed necessary, and performs other assessments and patient management tasks. Some time between the sixth and twelfth weeks after cataract surgery, the patient visits either an ophthalmologist or an optometrist to be measured for refractive errors of the eye and be given a prescription for glasses to correct the errors (American Optometric Association, August 1988). As soon as healing from cataract surgery is complete, the patient may return to his or her primary eye care provider (an ophthalmologist or optometrist) for routine eye care.

What is significant about each postoperative exam following cataract surgery is not simply what is examined but what judgments and adjustments in patient management are made at the time of the exam. Cataract surgery patients may develop any of a number of postoperative complications (as discussed in a separate section below) that must be managed appropriately if the surgery is to be as successful as possible. In the case of postoperative inflammation, for example, judgments have to be made about whether the inflammation is normal or is a sign of a serious problem. Although some inflammation after cataract surgery is inevitable, the degree of inflammation and its significance varies--depending on such things as the patient, the type of surgery, the difficulty of the lens extraction, and the skill of the ophthalmic surgeon, and on whether the patient develops an infection or other postoperative complication. In some patients, inflammation can be treated by adjusting steroid dosage,[28] but in other patients, excessive inflammation may be a sign of endophthalmitis, a vision-threatening intraocular infection (Jaffe, 1984; Piest et al., 1987). Endophthalmitis may require treatment with antibiotics injected into the eye or surgery; if appropriate treatment is not initiated within hours, the patient may lose the eye (Jaffe, 1984; Wong, 1988; Zach, 1988).

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[28] Many States do not allow optometrists to prescribe steroids (Stokes, 1988).

Other judgments and adjustments are also required. Some patients may require adjustments in their medications. Patients with glaucoma, for example, may need special management of intraocular pressure (Sherif and Dardenne, 1984). Reducing suture-induced astigmatism may require the surgeon to adjust or cut the sutures, and it is important that the adjustments be made at the proper time--cutting the sutures too early could overcorrect the astigmatism and make the wound leak, whereas cutting them too late could make the suture-induced astigmatism permanent (Nevyas, 1986).

Should a postoperative systemic problem related to pre-existing systemic disease (e.g., diabetes or hypertension) arise in a cataract surgery patient, the ophthalmologist's most likely and prudent course of action would be to send the patient to an internist (Greenberg, 1988).

EVALUATING ALTERATIONS IN THE TRADITIONAL MODEL OF CARE

The traditional model of care for cataract surgery patients--in which the attending ophthalmologist performs a preoperative evaluation and nearly all of the postoperative care--is rooted in surgical traditions that transcend the field of ophthalmology. According to the principles of the American College of Surgeons:

> The responsibility of a surgeon includes preoperative diagnosis and care, the selection and performance of the operation, and postoperative surgical care. . . . It is unethical to turn over postoperative care completely to the referring physician (Am. College of Surgeons, 1985).

The College of Surgeons further states:

> An ethical surgeon will not perform surgery at a distance from his usual location without personal determination of the diagnosis and the adequacy of preoperative preparation. He will personally render the postoperative care unless it is delegated to another physician as well qualified to continue the essential aspects of total surgical care (Am. College of Surgeons, 1985).

Given the long history, as well as the medical and ethical foundations of the traditional model of care for cataract surgery patients,[29] it seems reasonable to suggest that deviations from that model--some of which may already exist (American Optometric Association, August 1988; Greenberg, 1988, Mitchell, 1988, Myers, 1988)--should be closely scrutinized for effects on the quality of care.

OTA found no scientific studies of patient outcomes when optometrists provide preoperative or postoperative care for cataract surgery patients. Consequently, direct comparisons between the quality of perioperative care provided to cataract surgery patients by optometrists and ophthalmologists could not be made.

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[29] The legal aspects of this model of care are beyond the scope of this Staff Paper.

In the absence of scientific studies of outcomes associated with alterations in the traditional model of care for cataract surgery patients, conclusions about the medical wisdom of an expanded role for optometrists in the provision of preoperative or postoperative care for cataract surgery patients must be based on considerations of:

1. the nature of possible postoperative complications following cataract surgery and the skills that may be needed to help prevent or manage those complications;
2. differences in the training of optometrists and ophthalmologists that might affect the quality of care that these professionals are able to provide to cataract surgery patients in the perioperative period; and
3. general models of arrangements for the provision of postoperative care by a health professional other than the attending surgeon.

In considering the appropriateness of moving away from traditional arrangements for the provision of perioperative care to cataract surgery patients, a point that should be made is that the process of diagnosis differs significantly from the process of patient management. Diagnosis is the act of identifying a disease or condition from its signs and symptom. Patient management is the process a caregiver engages in when treating a patient for a diagnosed condition. In an initial diagnostic evaluation, the focus is on arriving at the correct diagnosis of a patient's condition; in managing a patient, the focus is evaluating the patient and undertaking whatever medical or other procedures are needed to help ensure a good outcome. Patient management is more complex than diagnosis in that it involves making repeated observations and judgments about a patient's condition and fitting them into an overall process of care. The preoperative evaluation of a surgical patient and the provision of postoperative care intended to ensure a good surgical outcome are both patient management tasks. Even though some of the procedures involved in diagnosis and the management of a surgical patient are similar, the skill and judgment required may be significantly different.[30]

Potential Postoperative Complications of Cataract Surgery

In terms of improving vision, cataract surgery is generally cited as being 94- to 96-percent successful (Allen and Hui-rong, 1987; Ruther and Black, 1987). Food and Drug Administration figures indicate that 84.6 percent of 50,537 study eyes with IOLs had 20/40 vision or better (Stark et al., 1983). It is important to note that these figures are based on care provided by ophthalmologists and give no indication of how many surgical or postoperative ocular complications or other problems were dealt with before the final outcome was achieved. The numbers also do not indicate how the success rate varies among elderly or other populations that are medically vulnerable because of concurrent ocular or systemic disease.

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[30] In diagnosis, physical examinations and diagnostic testing are used to develop and then narrow the list of possible causes of disease. In managing patients' disorders, the same procedures are used to assess the effectiveness of treatment and to measure the success of alternative manipulations.

Cataract surgery involves numerous types of postoperative complications. Examples of a few such complications are shown in table 3. These include endophthalmitis, severe postoperative inflammation, corneal edema, bullous keratopathy, pupillary block, secondary glaucoma, intraocular hemorrhage, wound leakage or rupture, cystoid macular edema, detached retina, pupillary displacement, iris prolapse, subluxation or dislocation of the lens, touching of the cornea by the IOL, and opacities of the posterior capsule (Jaffe, 1984; Nevyas, 1986; Safir, 1983).

Table 3.--Examples of Postoperative Complications Associated With Cataract Surgery

Endophthalmitis--Endophthalmitis is a severe, sometimes painless, intraocular infection that can be caused by any of several bacterial or fungal micro-organisms. It may cause a violent inflammatory reaction in the eye and can produce loss of vision. A patient with endophthalmitis should be seen by an ophthalmologist within hours, so that appropriate treatment with systemic antibiotics (sometimes injected into the eye), surgery, or other means can initiated before there is permanent loss of vision (Deutsch and Goldberg, 1984, Jaffe, 1984; Mauriello, et al., 1983).

Severe inflammation--A certain degree of inflammation after cataract surgery is normal. In some cases, severe intraocular inflammation that resembles endophthalmitis develops. Treatment of severe postoperative inflammation often involves the use of steroids (Jaffe, 1984).

Corneal edema and bullous keratopathy--Corneal edema, swelling in the layers that make up the cornea of the eye, is one of the most serious complications of cataract surgery. The more traumatic the surgery, the more edema will occur; edema may also occur when there is sharply raised pressure. If edema lasts longer than a few days, there may be serious corneal damage, and the patient should get medical or surgical treatment. In the worst cases, corneal edema may develop into bullous keratopathy and require a corneal transplant (Jaffe, 1984; Nevyas, 1986).

Pupillary block--Pupillary block occurs when the vitreous moves against the iris or interferes with communication between the anterior and posterior chambers. It happens most often when patients receive an anterior chamber IOL. If the surgeon doesn't take medical or surgical treatment to remedy pupillary block promptly, it can lead to chronic angle closure glaucoma (Jaffe, 1984).

Secondary glaucoma--Glaucoma is damage to the optic nerve caused by pressure in the eye greater than the eye can stand. The types of secondary glaucoma that may may arise following cataract surgery are numerous (e.g., malignant, sodium hyaluronate, hemolytic glaucoma; glaucoma associated with pseudoexfoliation, peripheral anterior synechias, pupillary block, epithelialization of the anterior chamber, fibrous ingrowth, phacoanaphylaxis, iris atrophy, postoperative inflammation, free vitreous in the anterior chamber, or hyphema). Treatment may require the prompt administration of topical or oral drugs to lower intraocular pressure or even surgery (Jaffe, 1984; Jensen, 1988).

Intraocular hemorrhage--Hemorrhage (bleeding) in the eye may take one of three forms: hyphema (bleeding into the anterior chamber), vitreous hemorrhage, or expulsive hemorrhage. Any of these may be extremely dangerous. The sudden occurrence of an expulsive hemorrhage, though extremely rare, is one of the most dangerous complications of cataract surgery. Surgical treatment must be initiated at once to prevent loss of the eye (Jaffe, 1984).

Wound rupture--A cataract wound may rupture or tear, often as a result of postoperative trauma. Most wound ruptures need to be promptly repaired by the surgeon (Lambrou and Kozarsky, 1987).

Cystoid macular edema--Cystoid macular edema involves swelling of the macula, the highly specialized part of the retina that is responsible for fine, high-resolution, central vision acuity. The problem is often associated with vitreous loss during surgery. The accumulation of fluid in the macula causes blurring of vision and may result in loss of central vision. If the problem does not resolve on its own, it may require treatment with an oral, nonsteriod anti-inflammatory drug such as indomethacin, local or systemic steroids, or even surgery (Nevyas, 1986; Jaffe, 1984; Safir, 1983).

Detached retina--The risk of retinal detachment is greater following intracapsular cataract extraction than following extracapsular extraction and is greater when a patient loses some vitreous during cataract surgery. If small peripheral holes are detected early, the surgeon may be able to do cryosurgery to prevent the holes from causing retinal detachment. If the retina does become detached, however, major intraocular surgery will be required to repair it (Coonan et al., 1985; Nevyas, 1986).

Pupillary displacement--The pupil may become distorted after surgery as a consequence of trauma or vitreous loss during surgery. Over time, the adhesion of vitreous strands to the retina can cause a detached retina. The surgeon may cut vitreous strands with a YAG laser (Nevyas, 1986).

Iris prolapse--Iris prolapse is the protrusion of a part of the iris through a wound in the cornea. Iris prolapse makes the eye vulnerable to infection. If the protrusion is large, the surgeon will have to excise or replace it (Jaffe, 1984; Nevyas, 1986).

Displacement of the IOL--An IOL sometimes become displaced from its normal position. If it stays in the area of the pupil, it is considered subluxated; if it is moves completely away from the pupil, it is considered luxated, or dislocated. The approaches for managing a patient with a displaced lens vary, depending in part on the position of the lens. In some cases, treatment may involve surgical removal of the displaced lens and the implantation of a new lens (Allara and Weinstein, 1987; Jaffe, 1984).

Touching of the cornea by the IOL--An IOL that makes physical contact with the cornea, even on an intermittent basis, is a serious problem, because the plastic used in most IOLs (PMMA) can kill the cornea's endothelial cells, eventually leading to opacification of the cornea and the need for a corneal transplant. An IOL that is touching the cornea must be removed by the surgeon.

Opacities of the posterior capsule--Approximately 40 percent of patients who have extracapsular cataract extraction surgery--the surgery now used in more than 90 percent of cases--will develop sufficient opacification of the posterior capsule as to necessitate a second procedure (e.g., YAG laser capsulotomy or surgical capsulotomy) to let light rays pass through undistorted (Safir, 1983).

SOURCES: N.S. Jaffe, Cataract Surgery and Its Complications (St. Louis, MO: C.V. Mosby Co., 1984; H.J. Nevyas, "How To Manage the Cataract Patient," Review of Optometry, pp. 46-56, July 1986; and A. Safir, "How Ophthalmology Has Changed During My Career," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.

Other postoperative complications associated with cataract surgery that are not shown in table 3 include delayed restoration, late loss, or late shallowing of the anterior chamber of the eye; Descemet's membrane detachment; choroidal detachment; postoperative optic neuritis; macular changes from postoperative hypotension; macular pucker and preretinal membrane; vitreoretinal traction syndrome; postoperative rupture of the anterior hyaloid membrane; hemosiderosis oculi; hemophthalmitis; uveitis; vitreous incarceration in the wound; sympathetic ophthalmitis; retained lens material; phacoanaphylactic uveitis; phacotoxic uveitis; epithelial cysts and downgrowth; fibrous ingrowth; IOL uveitis; IOL glaucoma; IOL hyphema; pupillary capture, and postoperative patient trauma (Hibbs, 1987; Jaffe, 1984).

Some of the available evidence on the rates of certain complications of cataract surgery is cited below. Since postoperative care has traditionally been provided by ophthalmologists, available evidence is based on cataract surgery patients for whom ophthalmologists provided the postoperative care.

Estimating overall complication rates among cataract surgery patients is difficult for several reasons. Rather than considering overall complication rates, most of the available medical literature considers rates of specific complications (e.g., Bartov et al., 1984; Coonan et al., 1985). Other studies do examine overall complication rates but only for particular surgical procedures or types of IOLs (e.g., Arnott and Condon, 1985; Kielar and Stambaugh, 1982; Shearing, 1983; Smith et al., 1987). For some complications (e.g., cystoid macular edema), the complication rates increase over time, so the longer the period of a study, the higher the rate of complication would be[31] (Jaffe, 1984; Lakhanpal and Schocket, 1987). Another problem is that the technology of cataract surgery is advancing so fast that if a study follows a large series of patients over a long period of time, the results of the study may be obsolete before the study is even complete.

Shearing did a study of postoperative complications among a group of 100 cataract surgery patients in whom a posterior chamber IOL was implanted between March 1977 and February 1978; these patients had no concurrent ocular disease at the time of their surgery and would generally be expected to do well (Shearing, 1983). Of the 100 patients in this study, 56 were followed for more than 4 years, and 35 were followed more than 5 years; 9 patients were lost to followup between 6 and 12 months. Of the patients who were followed, 6 developed retinal detachments, 4 developed secondary glaucoma, and 1 developed severe cystoid macular edema. Two of the patients developed problems related to the presence of the IOL. At the end of their followup, 90 percent of the patients followed in this study had visual acuity of 20/40 or better. Four patients had vision of less than 20/200, including three who were blind (one from retinal detachment, two from central vascular occlusions).

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[31] One could measure the complication rate per month of followup to address this problem, but OTA found no studies that used this approach.

Allen and Hui-rong analyzed complications in 416 eyes (in 358 patients) that underwent extracapsular cataract extraction surgery for simple senile cataracts from July 1977 through June 1983 (Allen and Hui-rong, 1987). The 416 eyes were divided into two groups: Group I for eyes that had no ocular disorders other than senile cataract at the time of cataract surgery (315 eyes, or 76 percent of the 416); and Group II for eyes that did have concurrent ocular disorders (e.g., diabetic retinopathy, repaired retinal detachment, glaucoma, macular degeneration, uveitis) at the time of cataract surgery (101 eyes, or 24 percent of the 416 eyes).[32] Some of the patients in each group had a posterior chamber IOL implanted in addition to extracapsular cataract extraction surgery (150 of the 315 eyes in Group I, and 36 of the 101 eyes in Group II). The incidence of certain postoperative complications for the two groups of eyes in Allen and Hui-rong's study, all of which were followed up for at least 3 months, is shown in table 4.

Table 4.--Incidence of Selected Postoperative Complications of Cataract Surgery
(measured as incidents per 100 eyes operated)

Complication	Allen and Hui-rong[a]	Stark et al.[b]
Endophthalmitis	.63 and 0	Not listed
Corneal edema	.63 and 1.0	.09 to 5.5
Retinal detachment	2.53 and .99	.76 to 3.5
Secondary glaucoma	.63 and 0	0 to 2.9
Cystoid macular edema	4.1 and 5.9	Not listed
Hyphema	1.26 and 0	Not listed
Subluxation of IOL	.95 and 0	.29 to 6.0
Opacification of the posterior capsule	19.0 and 17.8	0 to 20

[a] The figures from Allen and Hui-rong's study reflect incidents among eyes without concurrent eye disease at the time of cataract surgery (Group I) on the left and incidents among eyes with concurrent eye disease at the time of surgery (Group II) on the right. The figures for each group combine figures for patients who had extracapsular cataract extraction surgery alone and for patients who also received a posterior chamber IOL (see text for discussion).

[b] The numbers from Stark et al.'s study reflect the range of rates among eyes that underwent various methods of combined cataract extraction and IOL implantation (see text for discussion).

SOURCES: A.W. Allen and Z. Hui-rong, "Extracapsular Cataract Extraction: Prognosis and Complications With and Without Posterior Chamber Lens Implantation," Annals of Ophthalmology 19:329-333, September 1987; W. Stark, A.E. Maumenee, M. Datiles, et al., "Intraocular Lenses: Complications and Visual Results," Tr. Am. Ophth. Soc. 81:281-309, 1983.

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[32] The fact that 24 percent of eyes in this study had other eye disease at the time of cataract surgery suggests that success rates of cataract surgery measured only for healthy eyes offer just one part of the picture. No measures of the general health of the population receiving cataract surgery were found in any studies reviewed by OTA.

Allen and Hui-rong measured a broader range of complications than that shown in table 4 and found an overall postoperative complication rate of 30.2 incidents per 100 eyes operated.[33] Among patients without concurrent eye disease at the time of cataract surgery, Allen and Hui-rong found an overall postoperative complication rate of 31.4 incidents per 100 eyes operated. Among patients with concurrent eye disease at the time of cataract surgery, Allen and Hui-rong found an overall postoperative complication rate of 26.7 incidents incidents per 100 eyes operated. All of the postoperative complications that Allen and Hui-rong measured would require judgment concerning the most appropriate intervention. Clearly, however, some of the complications (e.g., opacification of the posterior capsule) are far less serious than others (e.g., endophthalmitis).

Table 4 also shows the incidence of postoperative complications among cataract surgery patients found in a study by Stark et al. (Stark et al., 1983). This study examined 1,344 eyes that underwent combined cataract extraction and IOL implantation: one group of 1,041 eyes that underwent extracapsular cataract extraction surgery and got a posterior chamber IOL, one group of 103 eyes that underwent intracapsular cataract extraction surgery and got an iris-clip lens sterilized by the dry-pack method, and one group of 200 eyes that underwent intracapsular cataract extraction surgery and got an iris-clip lens sterilized by the wet-pack method. For patients who got a posterior chamber IOL, the mean followup time was 12 months, with a range of 3 to 44 months. The age and ocular disease status of patients in the Stark et al. study differed from those of patients in Allen and Hui-rong's study. Furthermore, although the technology used in both studies was 1980s technology, the surgical technique and lens type in the two studies were not identical. Nevertheless, the incidence rates for certain complications found in the two studies did fall in similar ranges.

The data on postoperative complications in table 4 suggest that the successes of cataract surgery in terms of improving vision are achieved not just because of the good preoperative management and the technical quality of the surgical procedure but also because of the successful postoperative management of the ocular complications that develop. Some of the ocular complications of cataract surgery occur in the general population, but others (e.g., endophthalmitis, expulsive hemorrhage, iris prolapse, wound rupture, dislocated IOL) occur primarily in patients who have undergone cataract or other eye surgery (Jensen, 1988). A person who has been trained to perform eye surgery and has had clinical experience in the postoperative management of cataract surgery patients might be better able to recognize such complications than an individual without such training. A number of postoperative complications in cataract surgery patients are associated with certain types of surgical procedures or IOLs (e.g., the risk of a detached retina is greater following intracapsular extraction than following extracapsular extraction; pupillary block occurs more often when patients receive an anterior chamber IOL than when they receive a posterior chamber IOL) or with certain types of problems during surgery (e.g., endophthalmitis, cystoid macular edema, corneal edema, secondary glaucoma, retinal detachment, vitreous hemorrhage, and pupillary displacement may be associated with loss of vitreous during surgery) (Coonan, 1985; Jaffe, 1984). The surgeon who operates on a patient might be more alert to the possibility of these types of complications than a person who was not familiar with the specific procedure a patient underwent.

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[33] The data do not indicate how many individuals were involved. It is likely that some individuals had multiple complications. Thus, 30.2 incidents may have occurred in only 15 or 20 eyes.

Finally, it should be noted that some postoperative complications associated with cataract surgery require intervention that only an ophthalmologist or other physician can provide. The treatment of a detached retina, for example, involves eye surgery that only an ophthalmologist can perform. The treatment of bacterial endophthalmitis and other conditions may require the use of antibiotics, steroids, or other drugs with systemic effects that must be prescribed by a licensed physician.

Education and Clinical Training of Ophthalmologists and Optometrists

In the absence of scientific evaluations of data comparing the outcomes of care for cataract surgery patients treated in the perioperative period by ophthalmologists and optometrists, a question that arises is whether differences in the education and training of the two types of professionals might affect their ability to provide good quality perioperative care.[34]

There are no standardized tests or board exams taken by both ophthalmologists and optometrists, so the most plausible method of comparing the knowledge base of the two professions is to assess their educational and training programs. To compare the education and clinical training of ophthalmologists and optometrists, OTA reviewed literature pertaining to professional standards, literature from the professional organizations of both ophthalmologists and optometrists, and literature from several institutions that provide education and clinical training in either ophthalmology or optometry. In addition, OTA staff made direct observations at two institutions--at the ophthalmology residency program at Wills Eye Hospital in Philadelphia and at the Pennsylvania College of Optometry in Philadelphia.

Ophthalmology Education and Training

Ophthalmology is a surgical specialty of medicine and is regulated by State laws that govern medical practice. Ophthalmologists are licensed as medical doctors by State boards of medical examiners. There is no specific licensure of ophthalmologists (Stokes, 1988). Individuals who have 1) successfully completed specified medical, postgraduate clinical, and ophthalmologic residency training (see below), 2) received a valid and unrestricted license to practice medicine in the United States; and 3) passed written and oral examinations can be certified as diplomates by the American Board of Ophthalmology (American Board of Ophthalmology, 1987). That board is recognized by the American Board of Medical Specialties, which assists its members in the evaluation and certification of physician specialists (Council on Graduate Medical Education, 1988). The vast majority (90 percent) of ophthalmologists are board certified (Root, Sept. 29, 1988).

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[34] A recent OTA report on indicators of the quality of medical care found that physicians practicing in the area of their training were more likely to provide good quality care than physicians practicing in other areas (U.S. Congress, OTA, 1988).

In order to be certified by the American Board of Ophthalmology, an ophthalmologist must undergo an 8-year education and training program after college that includes training in systemic disease and experience with patients in a variety of settings, as well as specific classroom, clinical, and surgical training for the treatment of eye disease (American Board of Ophthalmology, 1987). The 8-year program involves three stages:

- o 4 years of medical school,
- o 1 year of postgraduate clinical training in a hospital-based program,
- o 3 years of training in a hospital-based ophthalmology residency program.

Medical schools in the United States, Canada,[35] and Puerto Rico are accredited by the Liaison Committee on Medical Education, a joint committee of the American Association of Medical Colleges and the American Medical Association (Carlson, 1988). Voluntary accreditation standards for graduate medical education and for residency training in the United States are set by the Accreditation Council for Graduate Medical Education. That organization is sponsored jointly by the American Board of Medical Specialties, the American Hospital Association, the American Medical Association, and the Council of Medical Specialty Societies (Council on Graduate Medical Education, 1988).

Prior to admission to medical school, a student is usually expected to complete a 4-year undergraduate degree, including specific courses in chemistry and other sciences, and must meet high scholastic and medical school entrance examination standards (Stokes, 1988). About 15 percent of medical schools allow students to enter after the third year of college (Association of American Medical Colleges, 1987).

Conventionally, the first 2 years at an accredited medical school emphasize coursework (lectures and laboratories) in sciences basic to medicine. In the first 2 years of medical school, a medical student typically gets between 1,500 and 2,000 hours of coursework. About 1,250 hours of this is coursework in basic medical sciences such as anatomy, pathology, physiology, microbiology, biochemistry, pharmacology, neuroscience, behavioral science, preventive medicine, and genetics (Assoc. of Amer. Medical Colleges, 1987). The rest is coursework in various topics related to medical practice.

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[35] Medical schools in Canada are coaccredited by the Liaison Committee and the Committee on the Accreditation of Canadian Medical Schools (Carlson, 1988).

The last 2 years of medical school emphasize clinical rotations in hospitals and other settings. During clinical rotations, a medical student gets an opportunity, under the direct supervision of faculty and resident physicians, to develop skills in examining and evaluating patients; during clinical rotations, a medical student has "limited opportunities to assume personal responsibility for patient care and generally do[es] not participate in the care of individual patients for an extended period of time" (American Medical Association, 1987). On average, a medical student spends about 80 weeks or, assuming a 40-hour week[36], 3,200 hours doing clinical rotations (Assoc. of Amer. Medical Colleges, 1987). On average, at least 50 of the weeks, or 2,000 hours, are spent doing rotations in basic medical specialties such as internal medicine, surgery, pediatrics, family/community medicine, and psychiatry); the remaining 30 or so weeks (1,200 hours) are spent doing rotations in various electives (Assoc. of Amer. Medical Colleges, 1987).

In preparation for becoming a licensed physician, a medical school graduate does a 1-year internship at a hospital in a field such as internal medicine, pediatrics, surgery, family practice, or emergency medicine. Traditionally, an intern is the first person "on call" to examine and admit patients to the hospital and is "on call" every third or fourth night to cover various activities in the hospital. In many cases, therefore, an intern works as many as 80 to 100 regular and on-call hours a week (Glickman, 1988; McCall, 1988). An intern who works an 80-hour week (e.g., 45 regular hours and 35 on-call hours) for 50 weeks would get a total of 4,000 hours caring for patients with a variety of medical problems. The certification requirements of the American Board of Ophthalmology specify that at least 6 months of an ophthalmologist's 1-year internship must be "broad experience in direct patient care" (American Board of Ophthalmology, 1987). An intern who works 40 regular hours a week for 26 weeks (6 months) gets 1,040 hours of clinical experience in the evaluation and treatment of patients with a variety of medical conditions. This figure--1,040 hours of experience in direct patient care--does not include any on-call hours and is therefore an absolute minimum.

To receive specialized hospital-based training in ophthalmology, a physician must enter a 3-year ophthalmology residency program. In order to be accredited, an ophthalmology residency program must include 360 hours of didactic instruction in basic and clinical sciences relevant to ophthalmology; 288 hours of clinical conferences attended by faculty and other resident physicians; and lectures, conferences, and a minimum of 50 hours in ocular pathology (American Medical Association, 1987). At some ophthalmology residency programs, these minimums are significantly exceeded. At the residency program at Wills Eye Hospital in Philadelphia, for example, students get 822 hours of didactic instruction in basic and clinical sciences, 504 hours of clinical conferences, and 210 hours of ocular pathology (Jeffers, 1988).

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[36] A 40-hour week does not include "on call" hours.

The core of an ophthalmology residency program, more important in some respects than didactic instruction, is clinical experience in managing patients with eye problems and in performing eye surgery. An accredited residency program offers a resident:

1) at least 3,000 outpatient visits distributed through a broad range of ophthalmic disease, with "major management responsibility under [faculty] supervision" in at least 2,000 visits,
2) surgical experience in performing and assisting at ophthalmic surgery of various types, including a minimum of 25 cataract procedures and 10 strabismus procedures,
3) consultation experience involving a minimum of 150 patients and covering a wide spectrum of ophthalmic diseases and ophthalmic manifestations of systemic diseases (American Medical Association, 1987).

Some ophthalmology residency programs offer clinical experience that far exceeds these accreditation minimums. At the residency program at Wills Eye Hospital in Philadelphia, for example, a resident manages, under supervision, about 15,000 patients with eye disease (Jeffers, 1988). A resident at Wills is involved in over 600 cases of eye surgery; in 350 to 400 of these (including 90 to 95 cataract surgeries), the resident is the primary surgeon and provides the patients' followup care; in the other cases, the resident assists during surgery (Jeffers, 1988).

Optometric Education and Training

In its 1976 report on optometrists (see app. A), HEW noted that the Institute of Medicine of the National Academy of Sciences had defined an optometrist as follows:

> The Doctor of Optometry (O.D.) is a health professional who performs eye examinations to determine the presence of visual, muscular, or neurological abnormalities, and prescribes lenses, other optical aids, or therapy such as eye exercises to enable maximum vision. Optometrists are trained to recognize disease conditions of the eye and ocular manifestations of other diseases, and to refer patients with these conditions to the appropriate health professional (U.S. DHEW, 1976, p. 21).

In 1976, neither this nor any other single definition of optometry was used in all State laws (U.S. DHEW, 1976). State laws at the time varied with respect to licensure requirements for optometrists, allowed scope of optometric practice, and continuing education requirements for optometrists (U.S. DHEW, 1976).

In 1988, the definitions of optometry and the licensure requirements for optometrists still vary from State to State. As a condition of optometry licensure, however, all States do require optometric training, as well as passage of the exam offered by the National Board of Examiners in Optometry and/or the exam offered by the State optometric board (Mays, July 8, 1988). Since 1976, many States have expanded the scope of optometric practice. As of June 1988, all States but Maryland[37] permitted optometrists to use certain drugs, under various controls, to diagnose eye problems; and 23 States permitted optometrists to use certain drugs, under various controls, to treat eye problems (Mays, July 8, 1988). In no State are optometrists licensed to perform surgery or to provide the full range of medical procedures that might be required to manage all of the ocular postoperative complications of cataract surgery.

Optometrists undergo a professional training program that is customarily 4 years in length.[38] There are 16 professional optometric degree programs in the United States (including Puerto Rico) and 2 additional programs in Canada (Mays, July 8, 1988). All 18 of the programs are accredited by the American Optometric Association's Council on Optometric Education (Council on Optometric Education, August 1988), which is a member of the Council on Postsecondary Accreditation (Mays, July 8, 1988). Furthermore, all schools and colleges of optometry are regionally accredited by the same agency that accredits other colleges and universities in the region (Boerner, 1988).

An individual seeking admission to a professional optometric degree program must have a minimum of 2 years of college, although most of the applicants (77.7 percent) have a baccalaureate or higher degree (American Optometric Association, August 1988). Applicants are also required to take the optometry college admission test.

To receive accreditation from the Council on Optometric Education, an optometric degree program does not have to conform to externally imposed requirements for the curriculum or clinical training it offers its students:

> In its evaluation of an optometric educational program, the Council will consider the stated objectives, what it seeks to accomplish for the student, the profession, and the public, and how well it succeeds in realizing these objectives. . . . . The Council encourages curriculum experimentation, the development of institutional individuality, and the achievement of excellence without the establishment of uniformity (Council on Optometric Education, 1983/1984, pp. 24-25).

During their 4-year training program, optometry students in different programs get varying amounts of didactic instruction (lectures and laboratories) in basic medical sciences, in ocular science, and in optics and lens design and application (Illinois College of Optometry, 1988;

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[37] A bill to permit the use of such drugs in Maryland was vetoed by the Governor in June 1988.

[38] Some professional optometric degree programs are 4-year programs, with training running 32 to 36 weeks per year; others are 3-year programs, with training running 44 to 48 weeks per year (Council on Optometric Education, 1983).

Pennsylvania College of Optometry, 1988; Southern College of Optometry, 1987). At the Pennsylvania College of Optometry, students get about 1,800 hours of didactic instruction, including about 700 hours of didactic instruction in basic medical sciences (e.g., gross anatomy, biochemistry, microanatomy, physiology, pharmacology, endocrinology), about 700 hours of didactic instruction in ocular science (e.g., glaucoma/ocular emergencies, neuro eye disease), and about 400 hours of didactic instruction in optics (e.g., advanced contact lenses) (Pennsylvania College of Optometry, 1988). At other institutions, the hours and courses offered are different (Illinois College of Optometry, 1988; Southern College of Optometry, 1987). At the Southern College of Optometry, for example, students receive more than 900 hours of didactic instruction in basic sciences (Southern College of Optometry, 1987).

In the latter 2 years of their training, optometry students typically get supervised placements in various college-based clinical settings and in off-campus clinical settings ranging from private optometric practices to institutional settings such as optometry clinics, nursing homes, health maintenance organizations, and hospitals (Boerner, 1988: Illinois College of Optometry, 1988; Mays, July 8, 1988; Mullen, 1986; Pennsylvania College of Optometry, 1988). Through these clinical placements, optometry students get an opportunity to provide eye examinations and fit patients for corrective lenses, with supervision from other optometrists. Optometry students also get some exposure to a smaller number of patients with eye disease, in some cases working under the supervision of physicians who hold faculty appointments with the college (Illinois College of Optometry, 1988; Pennsylvania College of Optometry, 1988; Southern College of Optometry, 1987). By the time they graduate, students at the Pennsylvania College of Optometry have seen a total of about 1,200 patients, some of whom have eye disease (Pennsylvania College of Optometry, 1988). Furthermore, they have followed some of the preoperative care and some of the postoperative care for about 8 to 60 patients undergoing eye surgery (Lewis, 1988). The clinical experience of students at other schools of optometry may very well differ.

Following graduation from an optometry program, some optometry students participate in a 1-year hospital-based or other optometric residency program (Mays, Sept. 22, 1988). Optometric residency programs are accredited by the American Optometric Association's Council on Optometric Education (Council on Optometric Education, 1985). Each of the accredited optometry residency programs is affiliated with a school or college of optometry, and many of the accredited programs are located at Veterans Administration facilities (Council on Optometric Education, 1987).

Comparison of Ophthalmologic and Optometric Training

OTA found that the training of ophthalmologists and optometrists differs quantitatively, and perhaps qualitatively, in at least three areas of potential significance to their ability to care for cataract surgery patients before and after surgery:

1) clinical training in the evaluation and treatment of patients with a variety of medical problems,
2) clinical training in the management of patients with eye disease, and
3) clinical training in the management of patients undergoing eye surgery.

As a physician, an ophthalmologist gets 3 years of clinical training (2 years of clinical rotations as a medical student and 1 year as an intern) in the evaluation and treatment of patients with medical problems. At no point in an optometrist's training is comparable clinical training in the evaluation and treatment of systemic disease offered. It can be reasonably hypothesized that clinical training in the evaluation and treatment of patients with systemic medical problems would affect the quality of a caregiver's judgments with respect to the management of a cataract surgery patient before and after cataract surgery. Systemic diseases such as diabetes mellitus, chronic obstructive pulmonary disease, and hypertension are common in candidates for cataract surgery, and such diseases can affect the risks and benefits of surgery, the likelihood of postoperative complications, and decisions about the postoperative management of ocular or systemic complications requiring the administration of antibiotics or other drugs with systemic effects. Even though an ophthalmologist may not actually treat a patient's systemic conditions, an ophthalmologist's training as a physician may enhance his or her ability to evaluate a patient's general health and make judgments about the need to refer the patient to an internist for the treatment of complications related to systemic conditions.

As an ophthalmology resident, an ophthalmologist gets 3 years of clinical training in the evaluation and treatment of patients with serious eye problems. An ophthalmology resident is responsible for making judgments about patients with ocular and related problems and for signing orders. By observing, treating, and taking responsibility for the care of patients with ocular and other problems, an ophthalmology resident gets a chance "to develop diagnostic, therapeutic, and manual skills and judgment as to their appropriate use" (American Medical Association, 1987). An optometrist gets substantial clinical training in the performance of eye evaluations but gets significantly less experience in the evaluation and treatment of patients with serious eye problems. It can be reasonably hypothesized that a person who has observed and managed a large number of patients with serious eye problems would be more likely to have developed skills in managing rare problems (or, in fact all such problems) than a person who has seen a smaller number of patients and has generally not managed their care.

Finally, the difference between ophthalmologists and optometrists in terms of their exposure to surgery and, more importantly, to patients who have recently had eye surgery is worthy of note. An ophthalmology resident performs cataract and other eye surgery and manages patients' postoperative care. An optometry student gets considerably less exposure to patients who have undergone eye surgery and does not have responsibility for managing patients' postoperative care.

General Models for the Provision of Postoperative Care by Caregivers Other than the Attending Surgeon

In the absence of scientific evaluations of the outcomes of perioperative care provided to cataract surgery patients by optometrists, it may be instructive to review models outside the field of ophthalmology in which caregivers other than the attending surgeon are involved in providing postoperative care. It is important to note, however, that none of models described below are exactly comparable to a situation in which an optometrist practicing at a site where the attending ophthalmologist is not readily available assumes responsibility for most of the cataract surgery patient's postoperative visits. Differences include such things as the complexity of the surgery that is performed, seriousness of possible postoperative complications, clinical training and experience of the supplemental caregivers, the practice setting and types and extent of supervision by the attending surgeon, and the State laws and regulations governing the scope of practice of the supplemental caregivers.

In some instances, part of a patient's postoperative care is provided by a physician other than the attending surgeon. In teaching hospitals, for example, a resident who was part of an operating team may provide followup care to a surgical patient for at least part of the postoperative period; typically, the care provided by the resident is reviewed and supervised by the attending surgeon. In the case of patient who undergoes cardiac surgery, the patient's cardiologist may take over some of the patient's postoperative care from the cardiac surgeon and be reimbursed by Medicare under the "-54"-modifier arrangements described earlier (Marsalek, June 15, 1988). In both these examples, the individuals providing postoperative care are physicians who, like the attending surgeon, have been trained in the evaluation and treatment of systemic disease and have had specific training in the area of medicine related to the patient's surgery. Also, in the first example, the resident providing postoperative care would know the details of the patient's surgery.

In some instances, health professionals who do not hold medical degrees but are trained to provide medical care and/or nursing care may provide some postoperative care after a physician has performed surgery.[39] Physician assistants, who have 2 years of academic and clinical training in a medical school setting (LeRoy, 1981), are specifically trained and registered in almost all States to provide certain services under the supervision of a physician (U.S. Congress, OTA, 1986). Physician assistants are considered by State laws to be agents of physicians (Cawley, 1988), and some States limit the number of physician assistants that a physician can supervise to one or two (Miller & Byrne, Inc., 1978). Physician assistants do provide some postoperative care (e.g., wound inspection), but the care is generally provided in a hospital under the supervision of the attending surgeon or another physician and is limited to services for which the physician assistant has been specifically trained. In some States, under some conditions, physician assistants can provide care if the physician is not on the premises (e.g., if an orthopedic surgeon is operating), but the physician assistant must be able to communicate with the physician immediately (Cawley, 1988). *Nurse practitioners*, who receive training beyond that required for an RN license in a particular specialty such as midwifery or family practice, may also provide some routine postoperative care in inpatient settings and in health maintenance organizations. In these settings, the surgeon or some other physician (e.g., a resident) would be available to deal with any problems that arose (Edmonds, 1988). *Visiting nurses* provide postoperative nursing care, but they have been specifically trained to do this, and in most States, the law requires that a physician authorize the plan for care and sign a certificate saying that he or she has seen the patient (Edmonds, 1988).

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[39] Dentists and podiatrists are trained and licensed to perform some limited types of surgical procedures, in some cases under medical supervision; as the attending surgeons, they also provide the postoperative care.

At least four potential areas of concern arise in circumstances where an attending surgeon shares postoperative care with a nonphysician caregiver at a geographically separate site. One concern is that when someone other than the attending surgeon provides a patient's postoperative care, *continuity of care* may be diminished. Having the attending surgeon or another person who is familiar with the exact nature of the surgery the patient underwent provide or supervise postoperative care enhances continuity. Surgical technique varies from surgeon to surgeon, and the response to surgery varies from patient to patient, so the quality of the postoperative observation may be related to the knowledge an observer has of the nature of the specific surgeon's technique in using a procedure and of the variables that would change a particular patient's postoperative response. Many would argue--and this argument is the basis of the traditional model of care--that the best and most consistent observer would be the operating surgeon. The surgeon would be aware of the usual response patients had to his or her own surgery. The surgeon would also be aware of any subtle variations in his or her technique that arose in a particular patient's case and that might alter the expected postoperative response. A second concern is that when a caregiver other than the attending surgeon who does not have medical or surgical training is involved in providing care to a surgical patient, *consistency of care* may be diminished. Consistency of care results when the examinations and diagnostic procedures given to a patient by different caregivers are uniform. It can occur only if all the caregivers who are evaluating a patient after surgery have had appropriate training, including an adequate amount of supervised clinical exposure to the types of patients who are to be assessed and to the possible complications that may arise. The caregivers must also be up-to-date in their training. In situations where nonphysician caregivers such as nurse practitioners or physician assistants are involved in providing postoperative care, consistency of care is enhanced by frequent onsite review by a physician, who has a close relationship with nonphysician caregivers.

A third concern is that when someone other than the attending surgeon is involved in the postoperative management of a surgical patient and the caregivers are at separate sites, there may be delays in care. If an emergency or other serious problem arises and the patient is not promptly transferred to a caregiver who has the medical or other skills needed to treat the problem, there may be irreversible damage to the patient's health. In order to prevent delays in care, cooperating caregivers must arrange for 24-hour patient coverage, and the patient must know who is responsible for care and be given easy and prompt access to the appropriate caregiver.

A fourth concern is that when a caregiver who does not have medical training is involved in the postoperative management of a surgical patient, the management of patients' systemic health problems may be inadequate. Physicians get education and clinical training that gives them exposure to patients with a range of systemic medical conditions that can affect surgical outcomes or be affected by certain types of drugs. A caregiver who has not had clinical training in the evaluation and treatment of systemic medical problems may not be able to manage patients' systemic problems following surgery appropriately.

The extent to which the four concerns just raised are addressed in existing comanagement arrangements for cataract surgery patients between optometrists and ophthalmologists has not been evaluated. As noted earlier, no scientific evidence to indicate what happens when postoperative care for cataract surgery patients is provided by someone other than the attending surgeon has yet been collected.

FINDINGS AND CONCLUSIONS

Congress requested that OTA assess the medical safety and appropriateness of optometric involvement in preoperative and postoperative care provided to cataract surgery patients. A report prepared by HEW in 1976 (U.S. DHEW, 1976) addressed several issues pertaining to optometric involvement in caring for Medicare patients, but did not present definitive conclusions on the role optometrists should play in preoperative and postoperative management of cataract surgery patients. Since 1976, there have been changes in the technology of cataract surgery and changes in Medicare laws, regulations, and carrier instructions that have led some optometrists and ophthalmologists to challenge the traditional model of perioperative care for cataract surgery patients. Thus, an evaluation of the safety and appropriateness of deviating from the traditional model by expanding optometric involvement in such care is now appropriate.

Assessing the appropriateness of preoperative and postoperative care for cataract surgery patients by optometrists is difficult because of the absence of scientific data about the outcomes of care for cataract surgery patients provided by optometrists and ophthalmologists. In the absence of scientific evidence, conclusions about the medical wisdom of moving away from traditional patterns of care must be based on considerations of the possible postoperative complications following cataract surgery, differences in the education and training of ophthalmologists and optometrists that may affect their ability to provide perioperative care, and general medical models for the provision of perioperative care by caregivers other than an attending surgeon.

With regard to preoperative care, it is the current assessment of OTA that a preoperative evaluation prior to cataract surgery must be done by the ophthalmologist who is to perform the surgery. Such an evaluation must include an evaluation of the risks and benefits of surgery to the patient and a decision as to the type of surgery. The preoperative evaluation must consider the patient's systemic health as well as the health of the patient's eye. Surgery is more than mere mechanics on an assembly line. Human individuality and biologic variability require a cognitive contribution to patient management, and this should be based on familiarity with the patient as well as medical science.

Allowing optometrists to engage in postoperative assessments of cataract surgery patients for all postoperative visits after the first one and to provide the visits at a site geographically separate from the attending ophthalmologist would be a significant departure from the traditional model of postoperative care for such patients. Potential risks of departing from the traditional model of postoperative care for cataract surgery patients include the following:

1. If an optometrist or other caregiver who is unfamiliar with the specific aspects of a particular patient's surgery is responsible for postoperative care, continuity of care and resulting quality of care may be adversely affected.
2. Optometric training may not give optometrists sufficient clinical exposure to the postoperative management of cataract surgery patients to allow them to make physical exams consistent with those of an attending ophthalmologist or to fit his or her exams into a regimen of postoperative patient management.
3. Optometric training does not give optometrists the medical or surgical skills needed to manage certain postoperative complications of cataract surgery. For patients who develop a problem that requires the involvement of the attending ophthalmologist (e.g., to prescribe systemic drugs that have to be prescribed by a physician or to perform eye surgery), delays as great as great as 12 to 24 hours might occur before the referral and consult by the attending surgeon could be completed, since few optometrists have 24-hour, weekend, on-call or emergency coverage for their patients. For most patients with most complications, a delay would be an inconvenience. In a few cases (e.g., the occurrence of endophthalmitis), a delay of several hours could result in the loss of an eye or have other serious consequences for the patient's health.

The extent to which these concerns have been addressed in existing comanagement arrangements for the postoperative care of cataract surgery patients has not been evaluated. In spite of the absence of a known risk, cautious medical practice suggests we should be aware of the potential risks of giving optometrists an expanded role in providing postoperative care for cataract surgery patients. Moving away from the traditional model of care without a scientific assessment of the likely effects on patient outcomes runs the risk of reducing the quality of care patients receive. A more prudent approach would be to allow cautious alterations in the traditional model--alterations that address plausible hypothesized concerns--and then to evaluate the effects.

APPENDIX A--SUMMARY OF HEW'S 1976 STUDY OF OPTOMETRISTS

In July 1976, the U.S. Department of Health, Education, and Welfare (HEW) issued a congressionally mandated study entitled "Report to Congress: Reimbursement Under Part B of Medicare for Certain Services Provided by Optometrists" (U.S. DHEW, 1976). That study, performed by the Health Resources Administration (HRA) with the aid of nine expert consultants and assistance from a variety of Federal agencies, specifically examined the question, "What services related to aphakic and cataract conditions currently covered under Part B of title XVIII of the Social Security Act, when provided by a physician, are appropriate for reimbursement when provided by an optometrist?" The only services for which optometrists could receive Medicare reimbursement at the time the study was undertaken were services related to establishing the necessity for prosthetic lenses.

Conclusions and Recommendations by the U.S. Department of Health, Education, and Welfare

The conclusions of the 1976 HRA study were derived from "factual information, analytic findings, and professional judgments assembled during the study" (U.S. DHEW, 1976). The major conclusions are quoted below.

> 1. Qualifications of optometrists. Optometry is a profession qualified to provide a broad range of services beyond refraction and the provision of eyeglasses. Furthermore, the services provided appear to be effective in patient management, including the management of aphakic and cataract patients. They are reasonable, nonexperimental, safe, and generally acceptable to the vision/eye care community and the public.
> 2. Services related to aphakic and cataract conditions. Many of these services are the same as the specific diagnostic, therapeutic, and consultative services currently covered under Part B of Medicare when provided to pre- and post-surgery cataract patients by ophthalmologists or other doctors of medicine and osteopathy.
> 3. Detection and diagnosis of disease. Evidence presented during this study supports the conclusion that optometrists, in general, are qualified to provide services for the detection and preliminary diagnosis of ocular disease and ocular manifestation of systemic disease. Referral, where indicated, is made

to ophthalmologists and other health care practitioners for definitive diagnosis and medical or surgical treatment.

4. Standards of procedure. Clinical standards committees of professional associations have identified effective instrumentation and procedures that are available to and utilized by optometrists which are effective in the diagnosis/detection of disease, notwithstanding limitation by certain State jurisdictions regarding the use of topical drugs.
5. Quality assurance. Quality assurance is attainable in the provision by optometrists of reasonable, safe, nonexperimental, and acceptable services to all patients, including the Medicare-eligible population. The development of criteria of care for diagnostic, therapeutic, and consultative services provided by optometrists, and similar to those existing for other professional groups, does appear feasible in both organized and independent health care settings. Such criteria currently exist in a number of individual situations or are in various stages of development.
6. Access to services. Vision/eye care services for aphakic and cataract patients, as well as for patients more generally, can be made more accessible to the Medicare-eligible population by providing reimbursement for services when provided by optometrists. In general, optometrists are more widely distributed geographically and practice in many smaller communities where other vision/eye care practitioners are not available.
7. Equity. Financial equity can be extended to those Medicare beneficiaries who currently obtain necessary and reasonable health services from optometrists but who do not currently receive the reimbursement to which they should be entitled.
8. Delivery patterns. It is reasonable to infer that inclusion of services under Medicare for aphakic patients when provided by optometrists would not significantly alter existing provider deliver patterns within the vision/eye care community. However, the impact upon such delivery patterns of the inclusion of services by optometrists for cataract patients, while likely to be small, is less clear.
9. Costs. It is reasonable to infer that the inclusion of services related to aphakic and cataract conditions when provided by optometrists would result in some added costs to the Medicare program. These added costs would be partly associated with Medicare enrollees currently served by optometrists without reimbursement, as well as those patients not now receiving care, who would do so as a result of the inclusion of such services under Medicare. Estimates suggest, however, that such added costs would note be significant in the context of overall Medicare costs for vision/eye care services and service benefits. This is viewed particularly so in the instance of extended reimbursement for services provided by optometrists to aphakic patients.

On the basis of the 1976 report, the U.S. Department of Health, Education, and Welfare recommended that those services covered under Medicare for aphakic patients and within the scope of practice of optometrists be reimbursable under Part B when provided by optometrists. The Department said it would be inappropriate to extend Part B reimbursement coverage to include services to cataract patients prior to surgery when provided by optometrists.

> Overall vision/eye care financed through Medicare should not be adversely affected by adjustments to the present system. The Department believes that the problems and numbers of aphakic patients are definable, significant, and yet manageable enough to warrant such an adjustment. With respect to services provided by optometrists to cataract patients . . . the Department believes that the resolution of a number of issues should precede further consideration of any extension of reimbursement. These issues include development of an operational definition of cataract, patient health care implications, delivery pattern changes, cost implications, appropriate patient cost sharing, and administrative design and control against abuse. . . . The attached [HRA] study did not address such concerns in detail (U.S. DHEW, 1976).

Recommendations by Expert Consultants to the HRA Study

Separate recommendations and concerns were advanced by the nine expert consultants (three optometrists, three ophthalmologists, one optometric educator, and two public representatives) who aided in the preparation of the HRA study. In reviewing the study materials, the consultants concluded that steps should be taken immediately to extend reimbursement under Part B for services provided by optometrists to both aphakic and cataract patients (U.S. DHEW, 1976). Citing as a rationale "considerations of patient needs, qualifications of optometry to provide services effective in patient management, and increased access of Medicare beneficiaries to vision/eye care services," the consultants to the study recommended that covered services related to aphakia and covered services related to cataract conditions, when provided by optometrists, be reimbursable under Part B. For the reasons cited above, the Department of Health, Education, and Welfare did not endorse the consultants' second recommendation.

The expert consultants to the HRA study also raised several other points. One of these, for example, was the inconsistent application of coverage and reimbursement policies by individual carriers. Another was the possibility for improving patient care by enhancing working relationships between optometrists and ophthalmologists. These relationships could be strengthened, it was suggested, by means such as developing joint educational programs at the undergraduate and graduate levels, establishing interdisciplinary clinics with optometrists and ophthalmologists working together, facilitating referral of patients between the optometrists and ophthalmologists when in the best relationship of the patient, and by joint development of quality standards for service and materials for by peer review mechanisms.

Limitations of the 1976 Study

At the time the 1976 study was undertaken, Part B coverage for cataract patients included, when provided by any doctor of medicine or osteopathy, 1) eye examinations, except that part of the examination related to refraction, if the examination was carried out in relation to a specific patient complaint; 2) surgical and related professional services carried out in connection with the removal of the lens; and 3) services in connection with the provision of both temporary and permanent prosthetic lenses, including fitting and providing the lenses themselves (U.S. DHEW, 1976). The only services for which optometrists might be reimbursed were dispensing services in connection with the actual fitting and provision of prosthetic lenses (U.S. DHEW, 1976). Neither the Department's recommendations nor the study on which those recommendations were based fully addressed the question of the appropriateness of having optometrists provide care for cataract surgery patients following their cataract surgery.

The recommendations and conclusions in the 1976 report were based on evaluations of the optometric and ophthalmologic practices that were in place at the time. The surgical techniques and the patterns of care for cataract surgery today are different from those of 1976. In 1976, cataract surgery was an inpatient procedure. The average hospital stay was 4.8 days in 1977 (Reuter and O'Sullivan, 1987). In the average case, an ophthalmologist performing the surgery would have been required to make in-hospital assessments for the first 5 days. As discussed in this OTA Staff Paper, technological changes since the 1976 report was issued have resulted in a shift of cataract surgery from inpatient settings to an outpatient settings. These changes mean that postoperative cataract care that would have been given by the attending surgeon as inpatient followup during days 1 to 5 after cataract surgery can now be given on an outpatient basis.

Licensing restrictions on optometric care have also changed since 1976. In 1976, only eight States allowed optometrists to use pharmaceutical agents for purposes of diagnosing ocular disease, and no States allowed optometrists to prescribe therapeutic drugs. Currently, 49 States and the District of Columbia permit optometrists to use some drugs, under certain conditions, to diagnose eye disease, and 23 States permit optometrists to use some drugs, under certain conditions, to treat eye problems (Mays, July 8, 1988).

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Washington, DC

Tom Lewis
Pennsylvania College of Optometry
Philadelphia, PA

Kenneth Marsalek
Office of Reimbursement Policy
Bureau of Eligibility, Reimbursement, and Coverage
Health Care Financing Administration
Baltimore, MD

Charles Mullen
The Eye Institute
Pennsylvania College of Optometry
Philadelphia, PA

Kenneth J. Myers
Optometry Service
Department of Medicine and Surgery
Veterans Administration
Washington, DC

Bernard Petashnik
Office of Reimbursement Policy
Bureau of Eligibility, Reimbursement, and Coverage
Health Care Financing Administration
Baltimore, MD

Elaine J. Power
Office of Technology Assessment
Washington, DC

Hunter R. Stokes
Secretariat for Governmental Relations
American Academy of Ophthalmology
Florence, SC

William Tasman
Wills Eye Hospital
Philadelphia, PA

Stanley M. Truhlsen
Advisory Committee for Ophthalmic Surgery
American College of Surgeons
Omaha, NE

Don Young
Prospective Payment Assessment Commission
Washington, DC

Melvin Wolfberg
Pennsylvania College of Optometry
Philadelphia, PA

Ira G. Wong
Ophthalmology Service
Kaiser Permanente Medical Care Program,
Northern California Region
Redwood, CA

Donald Zach
Massachusetts Eye and Ear Hospital
Boston, MA

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